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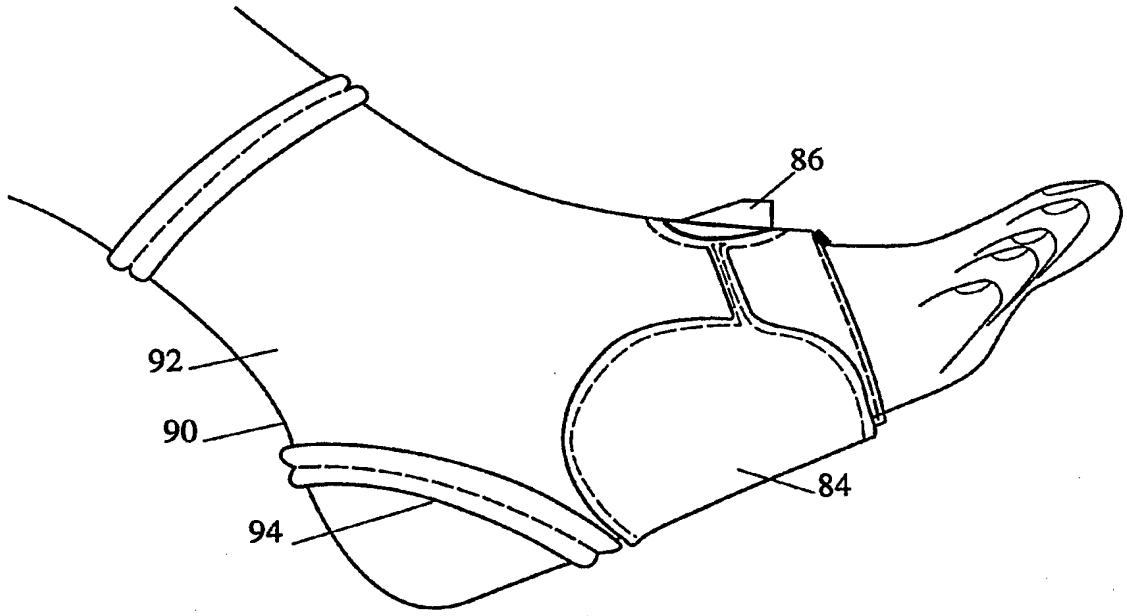

(57) Abstract

Disorder specific orthotic devices incorporating pulsed electromagnetic field therapy are comprised of an orthotic (90) anatomically designed to have a proper fit on a body region, limb or articulated joint and to have only one position in which the fit is comfortable and a pulsed electromagnetic field therapy module (86) attached to, mounted on or integrated into the orthotic and including an inductor (84) permanently positioned on the orthotic in the proper position to generate and administer the desired or prescribed electromagnetic field therapy. Each orthotic device thus comprises a simple, easy to use, therapeutic instrument that assures accurate, reliable and repeatable orientation and alignment of the electromagnetic field for proper treatment of a specific disorder.

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DESCRIPTION

ORTHOTIC DEVICES INCORPORATING PULSED ELECTROMAGNETIC FIELD THERAPY

Technical Field

The present invention relates to the field of electromagnetic field therapy ("EMFT") and pulsed electromagnetic field therapy ("PEMFT"), and in particular to orthotic devices incorporating pulsed electromagnetic field therapy apparatus and designed for the purpose of providing accurate and repeatable positional placement and alignment of the therapeutic module relative to the tissue requiring therapy.

Background Art

The therapeutic application of pulsed electromagnetic field therapy has been gaining credibility as an effective and beneficial therapy. Over 200,000 people have been involved in clinical trials that have established pulsed electromagnetic field therapy as a highly effective and appropriate therapy for a number of muscular skeletal disorders. Electromagnetic fields are propagated into the tissues requiring treatment by means of applying particular electrical characteristics to an inductive coil. The electromagnetic field is generally produced by applying a predetermined and pre-shaped electrical current to one or more inductive coil(s) in order to produce a desirable magnetic field with specified field characteristics. The magnetic field and therefore the applied therapy is generally referred to as the "waveform". The characteristics of the waveform are dependent upon the applied electrical current and the magnetic and physical characteristics of the inductor(s) or coil(s).

The parameters and characteristics of the resulting electromagnetic field are the subject of great academic and medical debate. See, for example, U.S. Patent Nos. 5,131,904, 5,100,373, 5,014,699, 4,911,686 and Australian Patent 52909/79. See also U.S. Patent Nos. 4,757,804 and 4,993,413. Nevertheless, certain electromagnetic field types have been approved by the American Food and Drug Administration for use in human subjects.

In recent times, pulsed electromagnetic field therapy has been proven through clinical trials to be highly effective in many disorders affecting the tendons and other connective and soft tissues of the body in addition to its known osteo active abilities. Of significant interest in soft tissue disorders are the clinical trials conducted by the Queensland Sports Federation Institute, Queensland University, and replicated by the SAB Sports Injury Clinic, University of Cape Town. In both cases, PEMF was found to be clinically effective in a range of chronic, acute and inflammatory disorders. Dr. Atlas & Dr. McArthur concluded . . . "PEMF effective in reducing pain, swelling and bruising, especially in acute injuries, and the effects were usually evident after the first or second treatments." Also, Dr. Harris of the Queensland University reported in a publication titled "A Report on a Clinical Trial of the Effects of PEMF on Tissue Injuries", that PEMF is beneficial in the treatment of tissue disorders.

While none of the trials propose an explanation for the means and mechanisms by which PEMF achieves this efficacy, an insight into the complex and varied beneficial cellular affects is provided by the double blind clinical trials of Ieron et al and Binder et al that revealed that PEMF was proactive in angiogenesis and chondrogenesis. In addition, Dr. Riva (ROME 1980)

stated . . . "from collagen in all its anatomical variations to the smooth muscular tissues, we draw the information that PEMF influences the activity of cellular elements and/or structures". In a report relating to PEMF and various soft tissue injuries (Physiotherapy 69/6) it was reported that PEMF "has a definite biological effect on recently injured soft tissues, especially in the reduction of swelling, the diminution of pain and in the improvement of function."

These reported effects are further supported by "PEMF Modifies Biomedical Processes" (Basset, Bioessays 6), Modulation of Collagen Production in cultured Fibro blasts by PEMF" (Murray/Farndale - 1985), "Treatment of Soft Tissue Injuries by PEMF" (Wilson, 1972), "PEMF Therapy of Persistent Rotator Cuff Tendinitis" (Binder, Parr, Hazelman - 1984). See also "Membrane Phenomena and Cellular Processes under the action of PEMF" (2nd International Congress of Magneto-Medicine 1980).

Of special relevance to bone fractures is "Fundamental and Practical Aspects of Therapeutic Uses of PEMF" by C.A. Bassett (Crit Reviews Biomedical Eng V17,5) and "The Development and Application of PEMF for Ununiting Fracture and Arthrodes" (Orth Clinics of NA V15,1) in which clinical, double blind trials and In-vitro studies are cited in support of the use of PEMF in cases of slow and ununiting fractures.

Of specific relevance is the Double Blind clinical trial by Sharai et al, (Bioelectrical Repair and Regrowth 1985,230) entitled "The Treatment of Non Uniting Fractures of the Tibia with PEMF" In all, there now exists a vast body of scientific research, as well as approval by the U.S. FDA, for the application of PEMF in cases of slow and non uniting fractures of the tibia.

Of interest in body joint disorders are the clinical trials by Trock, Bollet et al titled "A Double Blind Trial of the Clinical Effects of PEMF in Osteoarthritis". This trial reported "beneficial effects in the amelioration of symptoms, subjective improvement in functional ability and decrease in objective findings". Such positive effects are further supported by Bassett, (JAMA 1982), Mooney (Spine 1990), Goodman (Biochem 1989), De Loecker (Electromagnetic Med 1990), Murray (Biochem 1989), Grant (Ann NY Acc Sci 1991).

While the wealth of scientific evidence supports the improved efficacy of PEMFT, it has also been reported that such beneficial effects last only for around 4 months, especially in repetitive syndromes and recurring injury. This may necessitate repeated application of the therapy in order to provide long term or permanent benefit. As maximum therapeutic benefit is only provided when the electromagnetic fields are correctly positioned and aligned in relation to the tissues requiring treatment, this has traditionally required the application of PEMFT to be undertaken by a suitably skilled person with in-depth knowledge of anatomy, orthopaedics and electromagnetic therapy. Without these skills, there is the risk that a user may attempt to apply the therapy to alternative regions on the basis of perceived discomfort. By way of example only, a user suffering from tennis elbow or lateral epicondylitis may experience discomfort radiating down the muscles of the forearm and not necessarily from the point where the tendons require treatment. Without suitable direction, the user may inadvertently apply the therapy to an inappropriate region which may result in ineffective therapy and other unknown and unforeseen reactions.

To the present, there has been no simple device designed to deliver PEMF therapy in such a manner as to assure correct PEMF field orientation, alignment and positioning without the need for skills in anatomy, orthopaedics, physiology and electromagnetic therapy. Furthermore, there has been no simple device which allows comfortable and convenient administration of PEMF therapy by a relatively unskilled person or the patient him or herself.

Disclosure of the Invention

The object of the invention is to provide a series of simple, easy to use, wearable orthotic devices each incorporating one or more permanently affixed or integrated PEMF inductors and so designed that PEMF therapy for a specific disorder may be correctly administered by any sensible person without need for any skills whatever in anatomy, physiology, orthopaedics or electromagnetic therapy.

The concept of a more or less universal treatment device has been rejected and replaced by the concept of a series of disorder specific wearable orthotics each designed for PEMF therapy of a specific disorder, e.g., ankle inversion, achilles tendinitis, hamstring injuries, soft tissue disorders of the shoulder, etc.

In particular, the invention provides a plurality of disorder specific orthotic devices incorporating pulsed electromagnetic field therapy and each comprised of an orthotic anatomically designed to have a proper fit on a body region, limb or articulated joint and to have only one position in which the fit is comfortable, and a pulsed electromagnetic field generating inductor attached to, mounted on, integrated into, or otherwise permanently positioned on the orthotic in the proper location to generate and administer the desired or prescribed electromagnetic field therapy to specific

body tissues. Each orthotic device comprises a simple, easy to use, therapeutic instrument that assures accurate, reliable and repeatable orientation and alignment of the electromagnetic field for proper treatment of the specific disorder.

Each orthotic is anatomically designed to conformably embrace a specific body region, limb or joint. The orthotic includes means to insure that the orthotic can have only one position of comfortable fit. For an ankle or foot orthotic, this could include a heel cutout to embrace the heel or one or more toe embracing portions; for the knee joint, a patella cutout; for the elbow, an olecranon cutout; for the hand and wrist, a thumb cutout, etc. Where no body protuberance is available to establish a proper fit, ribs, ridges or seams that would impinge uncomfortably on the body unless properly positioned could be employed. However, whenever possible, it is preferred to utilize a characteristic of the user's anatomy to insure proper orientation of the orthotic on the body.

Each orthotic device is further comprised of a PEMFT module comprised of an inductor of the size, shape and inductive characteristics required or prescribed for therapeutic treatment and rehabilitation of a specific disorder. A power supply and wave form generator adapted to energize the inductor in the manner necessary to generate the desired or prescribed electromagnetic field may also be associated with the orthotic device, or alternatively may be separate from the orthotic.

The inductor is permanently affixed to, mounted on or integrated into the orthotic in proper orientation and alignment for administration of the prescribed electromagnetic field to the specific body tissues. Because the orthotic has only one position of comfortable fit and the inductor is permanently affixed

to the orthotic, the inductor will be correctly oriented to the tissue to be treated every time the orthotic is applied to the user's body. Consequently, alignment and orientation of the inductive field is accurate, reliable and repeatable. Thus, a user may administer the therapeutic treatment herself or himself without need for expert assistance.

The wave form generator may be located on the orthotic contiguous to or remotely from the inductor, or may even be located remotely of the orthotic if so desired.

The wave form generator(s) and the inductor(s) employed in practice of the invention are designed specifically for the propagation of harmonic free, therapeutic, extremely low frequency ("ELF") electromagnetic fields for application at distances of less than $\lambda/6$ (1/6 wavelengths), i.e. in the "Near Field" as it is commonly known. Otherwise, the nature and characteristics of the applied waveform or electromagnetic field are not a part of the present invention. The nature and characteristics of the electromagnetic fields are recommended and approved by statuary bodies in various parts of the world and may change from time to time as knowledge increases. For this reason, the present invention does not specify or claim any proprietary electromagnetic field characteristics. It is envisaged that many different field characteristics may be produced by the present invention by modification of the circuitry and the design of the components of the field module. Such modifications to the componentry or their values do not in any way reduce or negate the objectives of the present invention.

The invention thus provides a series of disorder specific orthotic devices incorporating extremely low frequency pulsed electromagnetic field therapy that are

simple, easy to use, and provide for proper administration of the prescribed therapy without need for any knowledge of anatomy, physiology, orthopaedics or electromagnetic field therapy.

These and other objects and advantages will become apparent from the following detailed description as considered in conjunction with the accompanying drawings.

Brief Description of the Drawings

Figure 1 is a plan view of a first embodiment of an electromagnetic field inductor coil suitable for use in practice of the invention;

Figure 2 is a plan view of a second embodiment of an EMF inductor coil suitable for use in practice of the invention ;

Figure 3 is a perspective view of a third embodiment of an EMF inductor comprising two coils arranged in overlapping relationship;

Figure 4 is a perspective view of one embodiment of an electromagnetic field therapy module comprised of an inductor and a self-contained power supply or wave-form generator for energising the inductor;

Figure 5 is a perspective view of a second embodiment of electromagnetic field therapy module comprised of an inductor and a power supply or wave form generator separate from the inductor and adapted to be located near or at a distance from the inductor;

Figure 6 is a perspective view of a third embodiment of EMFT module comprised of the Figure 3 inductor and a separate power supply or therapeutic wave form generator;

Figure 7 illustrates schematically one manner of encapsulating the module of Figure 5 or Figure 6 for subsequent association with an orthotic device;

Figure 8 illustrates schematically one manner of encapsulating the module of Figure 4 for subsequent association with an orthotic device;

Figure 9 is a side view of an orthotic device incorporating pulsed electromagnetic field therapy means for treatment of planar fascitis of the foot;

Figure 10 is a side view of an orthotic device incorporating pulsed electromagnetic field therapy means for treatment of achilles tendinitis;

Figure 11 is a side view of an orthotic device incorporating pulsed electromagnetic field therapy means for treatment of ankle inversion;

Figure 12 is a perspective view of an orthotic device incorporating pulsed electromagnetic field therapy means for treatment of ankle inversion;

Figure 13 is a rear view of an orthotic device incorporating pulsed electromagnetic field therapy means for treatment of gastrocnemius/achilles tendon musculotendinous;

Figure 14 is another rear view of an orthotic device incorporating pulsed electromagnetic field therapy means for treatment of gastrocnemius/achilles tendon musculotendinous;

Figure 15 is a side view of the orthotic device of Figure 14;

Figure 16 is a front view of an orthotic device incorporating pulsed electromagnetic field therapy means for treatment of tibia fracture;

Figure 17 is a side view of the orthotic device of Figure 16;

Figure 18 is a rear view of an orthotic device incorporating pulsed electromagnetic field therapy means for treatment of the hamstring and quadriceps muscle groups;

Figure 19 is a front view of an orthotic device incorporating pulsed electromagnetic field therapy means for treatment of the hamstring and quadriceps muscle groups;

Figure 20 is a front perspective view of an orthotic device incorporating pulsed electromagnetic field therapy means for treatment of groin injuries;

Figure 21 is a front view of an orthotic device incorporating pulsed electromagnetic field therapy means for treatment of knee injuries;

Figure 22 is a side view of the orthotic device of Figure 21;

Figure 23 is a front view of an orthotic device incorporating pulsed electromagnetic field therapy means for treatment of patella-femoral trauma;

Figure 24 is a side view of the orthotic device of Figure 23;

Figure 25 is a front view of an orthotic device incorporating pulsed electromagnetic field therapy means for treatment of patella tendon trauma;

Figure 26 is a side view of the orthotic device of Figure 25;

Figure 27 is a front view of an orthotic device incorporating pulsed electromagnetic field therapy means for treatment of the lumbo-sacral region;

Figure 28 is a rear view of an orthotic device incorporating pulsed electromagnetic field therapy means for treatment of the lumbo-sacral region;

Figure 29 is a front view of an orthotic device incorporating pulsed electromagnetic field therapy means for treatment of soft tissue pain syndromes of the shoulder;

Figure 30 is a rear view of the orthotic device of Figure 29;

Figure 31 is another front view of an orthotic device incorporating pulsed electromagnetic field therapy means for treatment of soft tissue trauma to the shoulder;

Figure 32 is a front view of an orthotic device incorporating pulsed electromagnetic field therapy means for treatment of supraspinatus tendinitis and rotator cuff pain syndrome;

Figure 33 is a rear view of the orthotic device of Figure 32;

Figure 34 is a front view of an orthotic device incorporating pulsed electromagnetic field therapy means for treatment of soft tissue cervical spine pain syndromes;

Figure 35 is a rear view of the orthotic device of Figure 34;

Figure 36 is a perspective view of an orthotic device incorporating pulsed electromagnetic field therapy means for treatment of lateral epicondylitis;

Figure 37 is a perspective view of an orthotic device incorporating pulsed electromagnetic field therapy means for treatment of medial epicondylitis;

Figure 38 is a perspective view of an orthotic device incorporating pulsed electromagnetic field therapy means for treatment of soft tissue wrist pathologies; and

Figure 39 is a schematic illustration of a modification in the relationship between the orthotic device and the waveform generator that can, if desired be adopted in respect of any or all of the orthotic devices illustrated in Figures 9-38.

Best Mode for Carrying Out the Invention

The following is a detailed description of several embodiments of the invention that are presently contemplated by the inventors to be the best mode of carrying out their invention.

Figures 1, 2 and 3 illustrate the inductive coils or inductors preferred for use in practice of the present invention. These inductors are the subject of applicants' copending application PCT/IB94/00216, filed 07 June 1994, incorporated herein by reference, and to which reference is made for a more thorough and detailed description. As pointed out in said application, these inductive coils are designed specifically for the propagation of harmonic free, therapetuic, extremely low frequency ("ELF") electromagnetic fields for application at distances of less than $\lambda/6$ (1/6 wavelengths), i.e., in the "Near Field" as it is commonly known. The present application is likewise directed to extremely low frequency pulsed electromagnetic fields, i.e., ELF-PEMF.[1]

Referring to Figure 1, there is shown a planar focal inductor 10 comprising a single continuous 1filament 12 of conductive material, wound spirally into a flexible coil and having an inner perimeter or diameter 14, an outer perimeter or diameter 16, and a void central region 18. The inner perimeter or central void is of a diameter d(v) that is from about 15% to about 40% of the outer perimeter diameter, i.e., the total inductor diameter d(t). This arrangement produces a uniform and focused electromagnetic field with minimum self induction. For many applications, a dimension d(v) equal to about 30% of the dimension d(t) is advantageous.

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[1] In PEMF therapy, an extremely low frequency is generally deemed to be one kilohertz (1 kHz) or less.

The conductive element 12, be it monofilament wire, multi-strand wire or etched copper track, is so displaced as to assure intimate horizontal contact with minimal vertical proximity. The inductor design and layout serve the purpose of propagating therapeutic time varying electromagnetic fields when energized by a suitable driver circuit, such as any of those known to the art. The type of driver circuit or waveform/frequency generator is not essential to the invention. Any suitable waveform generator known to the art may conveniently be used with the inductor coil, because the coil has the capability to propagate more than one frequency component.

When used for purposes of propagating therapeutic electromagnetic fields into tissues under treatment, the inductor provides centrally focused time varying magnetic fields with fast rise times and minimal harmonic ringing or distortion, especially during periods of magnetic field collapse.

The inductor may be deployed either as a single coil inductor, or as a multiple coil inductor having the coils disposed in the Helmholtz configuration, which is well known in the art, or in an overlap manner, in order to produce a magnetic flux density more suitable to the treatment of a broader range of tissues and disorders. The inductor provides such variants in utility while remaining less bulky and more comfortable than traditional inductive means. Moreover, due to its flexibility and formability, the inductor is adapted to be easily and conveniently integrated into wearable orthotics.

Figure 2 graphically illustrates a planar focal inductor 20 comprised of a flexible planar dielectric substrate 21 bearing a thin layer of copper which has been etched to form a continuous conductive spiral coil

or track 22. The coil or track has an inner perimeter or diameter 24, an outer perimeter or diameter 26 and a substantially void central region 28. The relationship between the diameter of the void central region and the outer diameter of the coil is the same as in the embodiment of Fig. 1. The inner perimeter, more specifically the terminal end of the inner winding of the coil, is provided with an electrical terminal 24a preferably positioned on the substrate 21 within the void region 28. Similarly, the outer perimeter, i.e., the terminal end of the outer winding of the coil, is provided with an electrical terminal 26a suitably located on a radial tabular extension of the substrate 21. A coil energizing source of power is thus readily connected to the inductor.

Instead of an etched copper track, the coil may be formed of other conductors appropriately bonded or adhered to the flexible substrate. The substrate may comprise any of the nonconductive, nonmagnetic dielectric sheets and films conventional in the art, such as polyamide, polycarbonate, polyruethane, PCB or silicone rubber. The inductor is thus easy to apply to and may readily be integrated into a wearable orthotic. The construction shown in Figure 2 provides the same benefits of minimum self-induction and focused magnetic densities as obtained with the construction of Figure 1.

Figure 3 shows a further inductor 30 in which two coil units 32a, 32b are utilized. The coils may be of the same construction as described in conjunction with either Figure 1 or Figure 2. In the embodiment illustrated, the units 32a, 32b have been overlapped so that the outer perimeter of each coil is aligned with the inner perimeter of the other coil. This arrangement further enlarges the overall flux density regions obtainable. Any number of individual units may

be overlapped to create a single implementation of the present invention, although non-overlapping or Helmholtz coil configurations may also provide similar benefits.

For purposes of commercial practice of the invention, each inductive coil preferably comprises a planar, annular, monofilament, multi-turn, spirally wound, single or double layer coil comprised of from about 100 to about 265 turns of 0.265 to 0.50 mm diameter PEI insulated copper wire; the coil or coils having an outer diameter appropriate to the target tissues under treatment and an inner diameter equal to 15% to 40% of the outer diameter. The coils may also be provided in elliptical or elongate form if appropriate to the target tissues. For purposes of use, the coil(s) is(are) conveniently enclosed or encapsulated in a protective cover, as will be described.

Referring now to Figure 4, a therapeutic ELF-PEMFT treatment module 40 is shown as comprising a dielectric substrate 42, an annular coil 44 formed in accordance with Figure 1 or Figure 2 on the substrate, electronic current shaping and waveform generating circuitry 46 mounted on the substrate within the void central region of the coil, and a power receptor or receptacle 48 mounted on the substrate adjacent the peripheral edge of the coil. The outer diameter of the coil 44 is such as is appropriate to the nature and type of the target tissues to be treated and the diameter of the central void area is such as to produce a uniform and focused electromagnetic field. The receptor plug 48 allows power from external sources to be conventionally applied to the PEMFT module. D.C. power may be obtained from power mains via a step down transformer, or from a battery pack, or from an internal or external rechargeable or disposable portable battery.

The circuitry 46 comprises an electronic driver suitably including timing means and a transistor based current driver means for appropriately shaping the current delivered to the inductor to provide for the frequency (timing), amplitude (current value) and duty cycle prescribed for the PEMFT treatment to be administered. As previously noted, the specific circuitry utilized is not critical to the practice of the present invention.

A second embodiment of ELF-PEMFT module is shown at 50 in Figure 5, wherein the electronic current shaping and waveform generating circuitry 56 is separated from the inductor coil 54. In this embodiment, the circuitry is mounted on a self-supporting circuit board 57 which also mounts a power receptacle 58 for receiving power from an external D.C. source. The circuitry 56 and receptor 58 are suitably enclosed within a protective housing or cover 59 which attaches in conventional manner to the circuit board 57. The module 50 may appropriately be assembled by inserting or encapsulating the inductor 54 in a fabric, foam or dielectric film pocket, securing the circuit board 57 to the surface of the pocket (as shown for example in Figure 7) and connecting the circuitry 56 to the inner and outer peripheral ends of the coil 54 as indicated in Figure 5.

Referring to Figure 6, a third embodiment of therapeutic ELF-PEMFT module 60 is comprised of a multiple coil inductor 64 such as that disclosed in Figure 3 and an electronic driver assembly 66 similar to that illustrated in Figure 5. As shown and as previously described, the inductor is suitably comprised of two overlapping inductor coils 64a and 64b, and the waveform generator is comprised of a self-supporting circuit board 67, appropriate electronic circuitry 66, a power receptor or receptacle 68, and a protective cover or housing 69.

As illustrated in Figures 7 and 8, the inductor and the waveform generating assembly are appropriately inserted in a pocket 82 formed of dielectric film, fabric or orthotic material which is provided with a hole or aperture through which the power receptacle extends so as to accommodate connection of the module to an external power source. Where the power module is separate from the inductor, as in Figures 5 and 6, the inductor and the circuit board are preferably each individually physically secured to the material forming the pocket. Alternatively, the inductor may be encapsulated in a first pocket and the circuit board and circuitry may be encapsulating in a second pocket for mounting the same remotely of the first pocket. While stitching has been illustrated in Figures 7 and 8 as an appropriate mode of securement, any attachment means that provides positional stability may be employed.

The pocket 82 thus provides a contained ELF-PEMFT therapeutic module that can conveniently be attached to an orthotic device whether the contained module is of the type shown in Figure 4, Figure 5 or Figure 6. For convenience in the following description of specific therapeutic applications, the contained module, regardless of specific type, will be indicated and described generically by the reference numeral 80 if both are incorporated in a single module. However, if the two components are separate units, the inductor coil unit will be indicated by the reference numeral 84 and the circuit module by the numeral 86.

Figures 9 to 38 illustrate orthotic devices incorporating ELF-PEMFT modules as above described for treatment and/or rehabilitation of specific disorders, namely, plantar fascitis (Figure 9), achilles tendinitis (Figure 10), ankle inversion injuries (Figure 11-12), injuries of the gastrocnemius/achilles

tendon musculotendinous junction (Figures 13-15), tibiafractures (Figures 16-17), injuries of the quadriceps and hamstring muscle groups of the thigh (Figures 18-19), soft tissue injuries of the groin (Figure 20), knee joint disorders (Figures 21-22) patella-femoral disorders (Figures 23-24) patella-tendon disorders (Figures 25-26), lumbo-sacral soft tissue pain syndromes (Figures 27-28), shoulder soft tissue pain syndromes (Figures 29-31), supraspinatus tendinitis and other rotator cuff pain syndromes and injuries (Figures 32-33), soft tissue cervical spine pain problems (Figures 34-35), lateral epicondylitis (Figure 36), medial epicondylitis (Figure 37) and soft tissue wrist pathologies (Figure 38). In all of the illustrated embodiments, a specifically designed orthotic serves as a positioning and alignment device for an attached inductor in order to establish and maintain accurate, reliable and repeatable positional placement, orientation and alignment of the inductive field relative to the intended treatment site.

Each of the orthotics is comprised of an anatomically designed body portion of a shape and size to encircle or intimately embrace the joint, limb or body portion to be treated and one or more of the PEMFT modules of Figures 4-8 permanently and securely affixed to the body portion in such location as to assure the correct orientation, alignment and positioning of the electromagnetic field relative to the tissues to be treated.

The body portion is preferably formed from an elastic, double-lined, neoprene or foam type of heat retentive material so as to incorporate into each device the therapeutic capabilities of such material, in particular the features of retained warmth, increased metabolism, musculatur support and overall activity modification, and in some cases haematoma

resolution and the imposition of limits on potentially exacerbating movements. Compression straps may also be employed to attain particular objectives. However, in appropriate circumstances, the elastic heat-retentive body portion can be supplemented or replaced by a rigid, partially rigid, articulated or adjustable brace. In any event, the body portion is anatomically designed, shaped and sized in such manner that a comfortable fit is obtained only when the orthotic is worn in accordance with the designer's instructions. Discomfort results from any other positioning. Consequently, with the orthotic in proper position, an inductor or inductors permanently affixed to the body portion will always be correctly aligned and positioned in relation to the tissues requiring electromagnetic field therapy. Field alignment and positioning are therefore reliable, accurate and repeatable. Consequently, ELF-PEMF therapy may be administered by persons, patients and users having no particular skills in anatomy, physiology, orthopaedics and electromagnetic field therapy.

The present invention thus provides a series of improved, disorder specific, comfortable and readily worn orthotic devices for the treatment and rehabilitation of such bodily disorders and that incorporates clinically proven therapeutic pulsed electromagnetic field therapy in a simple to use anatomically designed orthotic device that does not require the user to have any particular skills in the art of orthopaedics or electromagnetic therapy in order to gain maximum therapeutic benefit and effective treatment.

Prior to the present invention, there was no such simple device. Representative embodiments of the improved orthotic device of the invention will now be described in conjunction with Figures 9 through 38.

The orthotic device illustrated in Figure 9 is specifically designed for treatment and rehabilitation of plantar fascitis of the foot.

The longitudinal arch of the foot is supported in part by the fascia extending from the anterioinferior surface of the calcaneum to the heads of the metatarsals. A condition known as plantar fascitis occurs when this fascia is subjected to repetitive stress. The fascial fibres are traumatised and a healing reaction leads to the formation of scar tissue or a boney spur at the calcaneal attachment. The formation of the spurs or intra fascial scar correlates with persistent symptoms, or recurrences of symptoms. The symptoms are pain exacerbated by weight bearing. Activity is severely limited.

Treatments currently used include the use of anti-inflammatory medications, rest, the use of foot orthotics designed to relieve tension in the fascia, cryotherapy, ultrasound and interferential therapy.

Referring to Figure 9, there is provided an anatomically designed and shaped foot orthotic device 90 which is preferably of the closed ankle type, but which may be of the open type if deemed appropriate. The foot embracing body 92 of the orthotic is preferably formed from flexible heat retentive material. In the preferred embodiment, the power receptor plug, circuit board and associated circuitry 86 of the PEMF module are positioned on the upper portion of the orthotic with internalized connection to the inductor which is held in position by pocket 84 secured to the plantar, medial and/or lateral surfaces of the orthotic. The placement of the circuit components 86 is a matter of convenience and comfort as such positioning does not in any way impact on the efficacy of the invention. The electromagnetic inductor component 84 need not be in close proximity to

the driver component 86. The improvement in efficacy is obtained by the orthotic's accurate positioning of the inductor or inductors in relation to the plantar fascia tissues requiring therapy. Heel cutout 94 is provided for increased positional accuracy. Thus, accurate and repeatable positional placement and alignment of the inductor component is assured.

The orthotic device illustrated in Figure 10 is specifically designed for the treatment and rehabilitation of achilles tendinitis and other ankle disorders.

Achilles tendinitis commonly occurs just proximal to the calcaneal insertion in the portion of the tendon which is generally regarded as having compromised circulation in some patients. On occasions there is complete rupture of the tendon resulting in the need for surgery or serial casts. More commonly there is trauma to collagen fibers within the tendon resulting in an inflammatory reaction and the formation of scar tissues. This often becomes persistent and recurrent.

Treatment of tendinitis includes cryotherapy, the use of anti-inflammatory medications, rest, the use of heel raises, and stretching exercise regimes. While these methods assist in reducing syndromes, and the persistence or recurrence of injury, they do not substantially effect the natural history of the underlying pathology.

These modalities are primarily designed to reduce any haematoma, limit the reaction to injury and reduce symptoms. Existing orthoses are designed to assist in these matters and by doing so aid in rehabilitation. PEMF has been shown to minimise the reaction to the tendon trauma and modify regional circulation which all result in reduced syndromes and reduced recurrence.

The device illustrated in Figure 10 comprises an anatomically designed and shaped ankle orthotic device 100 having a body 102 comprised of flexible heat retentive material. Depending upon the nature and extent of the injury, the body 102 could be supplemental or replaced by a rigid, semi-rigid or adjustable ankle brace. In the preferred embodiment, there is one PEMF module 80, although it may be desirable to supply the orthotic with a plurality of such modules for treatment of various ankle disorders. The power receptor plug and associated circuitry is shown positioned near the upper margin of the orthotic. Such placement is a matter of convenience and comfort. The electromagnetic inductor means may be inserted in and attached to the orthotic via pocket 82 so as to overlie the achilles tendon region of the ankle. The design of the ankle orthotic is such that comfortable fit is only possible when worn in accordance with the designer's instruction and in this way, the electromagnetic fields will be aligned and positioned correctly over the tissues requiring therapy without the need for the user to have any particular skills. Heel cut-out 104 is provided for greater positional accuracy and stability.

The ankle orthotic device illustrated in Figures 11 and 12 is designed for the treatment and rehabilitation of inversion injuries of the ankle and related pathologies.

Inversion injuries of the ankle are among the most common injury in any given population group. These injuries are graded according to the degree of ligamentous damage to the lateral ligament complex of the ankle. By far the most common degree of injury is termed a grade one injury where the anterior talofibular ligament is disrupted.

This results in anterolateral swelling and pain with limitation of movement. Common treatment methods and modalities include the use of anti-inflammatory medications, cryotherapy, structured muscle rehabilitation regimes, strapping and bracing, elevation and rest. These modalities are primarily designed to reduce any haematoma, limit the reaction in injury and reduce symptoms. Existing orthoses are designed to assist in these matters and by doing so aid in rehabilitation.

Referring to Figures 11 and 12, there is provided an anatomically designed and shaped ankle orthotic device 110 having a body 112 which is preferably comprised of elastic heat retentive material. In the preferred embodiment, there is one PEMF module 80 on the device, although it may be desirable to supply the orthotic with a plurality of such modules. The power receptor plug and associated circuitry are preferably positioned on the upper or dorsal surface of the foot portion of the orthotic. The electromagnetic inductor assembly is of a size and shape to overlie the talofibular ligament area of the foot and ankle for proper PEMF therapy of the specific disorder.

The device illustrated in Figures 13-15 is a calf orthotic device particularly designed for the treatment and rehabilitation of injuries of the gastrocnemius/ achilles tendon musculotendinous junction.

It is relatively common for active people to incur an injury to the musculo tendinous function at the origin of the achilles tendon, in the posterior calf. This injury occurs during exercise and is associated with initiation of forward movement from the resting position. It is believed that this junction is susceptible to injury because of the relatively sparse vascularity. The injury is characterized by the sudden onset of pain exacerbated by walking or running. Power

of the ankle flexors is reduced. Episodically, the trauma to the tendon is such that the gastrocnemius profile changes as the muscles contract proximally.

The common treatment modalities include cryotherapy, rest, the use of heel raises and then rehabilitation regimes involving progressive stretching of the gastrocnemius complex. The injury involves tearing of fibers, intramuscular hemorrhage, and the formation of scar tissue which often becomes the center of an irritant focus. Rehabilitation can be lengthy.

Referring to Figures 13, 14 and 15, there is provided an anatomically designed and shaped calf orthotic device 130 having a calf encircling body 132 that is preferably of elastic heat retentive material. In the preferred embodiment illustrated, one PEMF module 80 is provided on the rear or posterior surface of the body 132. However, it may in some instances be desirable to supply the orthotic with a plurality of such modules. The power receptor plug and associated circuitry are positioned adjacent the upper margin of the orthotic. Such placement is, however, a matter of convenience and comfort. The electromagnetic inductor means may be inserted or attached to the orthotic via a pocket so as to overlie the gastrocnemius/achilles tendon musculotendinous junction. The calf orthotic device thus provides for increased metabolism, musculature support and overall activity modification and the therapeutic benefits resulting from the application of therapeutic extremely low frequency electromagnetic fields directly over the achilles tendon region.

The orthotic device illustrated in Figures 16 and 17 is designed particularly for the treatment and rehabilitation of the tibia and more particularly fractures of the tibia.

The tibia is frequently fractured. These fractures are either complete and result from specific trauma, or are partial and result from prolonged and/or recurrent stress.

The tibia is sometimes slow to unite. In particularly the junction of the middle and lower third has compromised circulation in some patients and this results in poor or delayed union. Electrical stimulation and ambulatory casts are used in order to stimulate bone growth.

In some patients prolonged stress leads to small hairline "stress fractures" of the tibia and these cause persistent pain particularly on exertion. In general, such fractures are treated by rest although a significant body of medical research has indicated that such rest may lead to a reduction in bone mass and general atrophy of the musculoskeletal soft tissues.

PEMFT has been shown to have significant osteogenesis properties that have proven to be highly effective in cases of fractures, especially those that are traditionally slow to unite. In addition, PEMFT has been shown to replicate many of the naturally occurring piezo electric signals required by the body in order to maintain musculoskeletal tissues during periods of rest.

Referring to Figure 16 and 17, there is provided an anatomically designed and shaped leg orthotic device 160 having a body portion 162 preferably of elastic heat retentive material, but which may be supplemental or replaced by a rigid tibia brace. Also, it may be desirable to extend the orthotic to encompass the knee region for additional positional accuracy and stability.

However constructed or fabricated, the body 162 is anatomically shaped and sized to encircle and intimately embrace the calf and tibia regions of the u user's let. A pair of elongate or elliptical inductors 164a and 164b are permanently affixed to the body so as to extend vertically along the leg on opposite sides of the tibia. The inductors embody the same technology as described in conjunction with Figures 1-3 and are decribed in specific detail in copending application PCT/IB94/00216.

Both inductors are suitably energised or driven by a single power supply unit 86 of the type shown in Figure 6. The power receptor plug and associated circuitry are suitably positioned on the lower portion of the orthotic as a matter of convenience and comfort.

By providing two elliptical or elongate inductors on opposite sides of the tibia, electromagnetic fields are generated along the length of the bone and over the adjoining muscles, tendons and associated tissues. The ELF-PEMFT fields will thus provide significant osteogenesis properties to stimulate repair of a fracture and to replicate natural piezo electric signals required to maintain musculoskeletal tissues during the period of recuperation and rehabilitation following a fracture of the tibia.

The orthotic device illustrated in Figures 18 and 19 is designed for the treatment and rehabilitation of injuries to the quadriceps and hamstring muscle groups.

It is generally accepted that the two most common soft tissue injuries of the thigh involve trauma to the quadriceps or hamstring muscle groups. The nature of these injuries are either contusion or tearing of the musculature and/or their associated tendons. These muscle groups have abundant circulation and trauma results in intramuscular bleeding. This in turn tends to lead to a haematoma which takes some time to resolve.

The associated symptomatology is reduced muscle power, restricted movement and pain on exertion. The summation of these is reduced performance in many athletes. Incomplete resorption of the haematoma and inappropriate or premature exertion may encourage the formation of immature scar tissue that will frequently result in persistent symptoms or recurrence of the injury.

Traditional treatments regimes include cryotherapy, massage, ultrasound, exercise and stretching regimes as well as the use of anti-inflammatory drugs. While these methods and modalities are primarily designed to minimise or resolve the haematoma, reduce symptoms and "down time", there is currently little scientific evidence to suggest they alter the underlying pathology.

Over the last 10 years or so, significant clinical and cellular research programs have demonstrated that pulsed electromagnetic field therapy has proven effective in soft tissue disorders that demonstrate a similar pathology to those encountered in injuries to the quadriceps and hamstrings muscle groups. In particular, PEMFT has been found to be effective in both chronic hamstring strain and the resolution of intramuscular haematomas.

Figures 18 and 19 are front and rear views, respectively, of an anatomically designed and shaped thigh orthotic device 180 which is designed for treatment of the hamstring and quadriceps muscle groups. The device includes a body portion 182 of the same type as previously described adapted to encircle and encompass the thigh of the wearer.

An ELF-PEMF therapy module 80 is permanently affixed to the orthotic body so as to be positioned over the thigh region of the user. The body holds the PEMF module and inductor positionally stable in the

desired location so that the electromagnetic fields will be aligned and positioned correctly over the tissues requiring therapy. For greater positional accuracy, the ELF-PEMF module could be incorporated in wearing apparel, such as snug fitting shorts like those shown in Figure 20.

The orthotic device illustrated in Figure 20 is designed for the treatment and rehabilitation of soft tissue injuries of the groin.

It is generally accepted that the clinical syndromes referred to as soft tissue injuries of the groin result from trauma to one of:

a. The pelvic origin of the thigh musculature including the quadriceps and abductor group of muscles.

b. The pelvis ligaments.

c. The inguinal insertion of the fascias associated with the abdominal wall.

The syndromes are characterised by persistent ache particularly on exertion, and particularly during the acceleration phase of running. The ache or pain frequently limits movement in terms of power and range of motion. These syndromes frequently lead to prolonged "down time" in performance athletes, as they tend to persist and recur.

Generally accepted therapies include ultrasound, interferential therapy, anti inflammatory medications, and exercise regimes. Infrequently, operative intervention is elected as the treatment of choice.

It is generally believed that these syndromes persist because there is poor healing in response to injury of the underlying tissues. Symptoms are reduced by heat, and this observation has lead to the widespread use of heat retaining groin shorts or orthotics made of heat retaining components. While such orthoses provide retained warmth, some physical support and motion modifications all of which are

beneficial, overall efficacy would be greatly improved with the integration of PEMFT. This is due to PEMF's ability to act directly on many aspects of the underlying pathology and the body's natural response to the initial trauma.

As shown in Figure 20, an improved orthotic device 200 for ELF-PEMFT treatment of injuries of the groin is comprised of a body 202 in the form of a snug-fitting lower torso and upper leg embracing pair of shorts or similar garmet. A pocket 84 containing one or more, and preferably a plurality of, electromagnetic inductor coils is permanently affixed to the body embracing garment 202 in such position or positions as to apply the desired ELF-PEMF therapy to one or more selected regions. One or more driver modules 86 for the inductors may suitably and conveniently be permanently affixed to the garment 202 in the vicinity of the user's waist.

The orthotic device illustrated in Figures 21 and 22 is designed for the treatment and rehabilitation of knee joint disorders.

Syndromes relating to knee pathology are most common amongst an active population. These fall into several categories.

a. Those associated with boney pathology.

b. Those associated with internal derangement or trauma to the cruciate ligaments, menisci, or severe trauma to the collateral ligaments.

c. Those relating to damaged articular cartilage.

d. Those relating to soft tissue inflammation or trauma.

The treatment of the disorders outlined in a & b involve mainly surgical techniques, while conservative management makes up the mainstay of treatments for disorders outlined in c. and d.

The most common conditions are osteoarthritis leading to loss of articular cartilage and minor injuries leading to inflammation of the synovioum. The conservative treatments of these conditions include the use of anti-inflammatory medications, exercise regimes, ultrasound, acupuncture, manipulation and rest. While these may reduce pain and diminish the inflammatory response, they frequently fail to alter the natural history of the underlying pathology, and in particular to halt the progressive nature of osteoarthritis.

Clinical trials and cellular research programs into the biological effects of PEMFT have been conducted for nearly 16 years and during this time, a vast body of supporting evidence has been generated that establishes that PEMF provides proactive therapeutic benefit over a range of disorders commonly encountered in the knee.

For the treatment of knee joint disorders, it is especially desirable to employ a knee embracing orthotic constructed from double lined heat retentive flexible neoprene type material for increased metabolism, musculature support and overall activity modification. Also, in the case of knee disorders, as well as ankle disorders, it is frequently desirable to incorporate an articulated or adjustable range of motion brace in the orthotic.

Referring to Figures 21 and 22, an anatomically designed and shaped knee orthotic 210 preferably comprises a knee brace 212 of the rear entry type that is preferably constructed from double lined neoprene type heat retentive material. Velcro straps or similar securing means 214 are provided to allow simple and ready affixing of the orthotic device over the knee region of the user and to assist in comfort and positional stability. Also, a patella cutout 216 is

preferably provided for increased positional accuracy. In the preferred embodiment, two inductors 84a and 84b are permanently affixed to the brace 212 on opposite sides of the knee. Both inductors are , or each inductor is, adapted to be energised from a single driver module 86 conveniently positioned on the brace below the patella region of the knee.

The orthotic device illustrated in Figures 23 and 24 is designed for the treatment and rehabilitation of patella femoral disorders producing peri-patella pain syndromes in the knee.

It is generally accepted that there exists a group of clinical syndromes related to pathology specific to the patella-femoral joint as distinct from the knee joint proper. These syndromes are characterised by anterior knee pain, peripatella tenderness and swelling.

The cause of these syndromes includes altered biomechanics associated with growth, direct patella trauma, overuse and degenerative change. The associated pathology includes an inflammatory response from the capsular structures adjacent to the patella and localized inflammation in the synovial tissue adjacent to the patella.

The syndromes are peri-patella pain exacerbated by knee flexion and particularly by walking up or down stairs or steep slopes. There is frequently a sensation of lightness and stiffness in the morning. The dominant sign is peri-patella tenderness and slight swelling.

The available treatments, methods and modalities are diverse. These include surgical correction of biomechanics, muscle rehabilitation regimes, the use of anti-inflammatory medications, taping, ultrasound, TENS and acupuncture.

While available treatment methods and modalities relieve symptoms and remove the underlying immediate cause of the condition, there is currently little correlation between their effects and the underlying pathology.

An anatomically designed and shaped knee orthotic device 230 for treatment of patella femoral disorders is illustrated in Figures 23 and 24. As in the device of Figures 21-22, the body 232 preferably comprises a knee brace of the rear entry type constructed of heat retentive material for increased metabolism, musculature support and overall activity modification. Velcro or similar securing means 234 are provided to allow simple and ready affixing of the improved orthotic device over the knee region of the user and to further assist in comfort and positional stability. A patella cutout 236 provides for greater positional accuracy when placed on the knee of the user.

In the preferred embodiment, a single inductor coil assembly 84 is permanently secured to the knee brace 232 in substantially concentric orientation to the patella opening 236, thereby to provide for efficacious ELF-PEMFT treatment of patella femoral disorders. The inductor is suitably energised from a power or driver module 86 secured to the brace below the patella opening.

The knee orthotic device illustrated in Figures 25 and 26 is designed for the treatment and rehabilitation of patella tendon disorders.

The device is very similar to those described in conjunction with Figures 21-24, except that the shape and location of the inductor assures accurate therapeutic field alignment, location and orientation for effective therapy of patella tendon disorders.

It is generally accepted that a specific group of clinical syndromes known as patella tendon disorders generally occur as a result of trauma to the collagen fibres making up the patella tendon which is the portion of the quadriceps tendon between the inferior pole of the patella and the tibial insertion.

This syndrome is frequently persistent or recurrent as the damaged collagen scars and in many cases acts as an ongoing irritant such that a cycle of pathology is established.

The condition is frequently associated with forced extension of the knee such as when jumping, hence its alternative name of "jumper's knee". Treatment commonly used includes anti-inflammatory medications, restricted activity, ultrasound and interferential therapy. Acupuncture is used less commonly.

It is generally accepted that it is beneficial to minimise the scarring resulting from the trauma to collagen fibres in the tendon. It is proposed that minimal scarring will prevent the cycle of progressive pathology and persistent clinical syndromes.

Referring to Figures 25-26, an anatomically designed and shaped orthotic device 250 for treatment of patella tendon disorders is constructed the same as the previously described knee orthotics except for the placement of the inductor 84 on the brace 252. Corresponding components are thus labeled with corresponding reference numerals.

In this embodiment of the invention, an inductor coil assembly 84 is secured to the brace 252 immediately below the patella of the knee and extends traversely across the tissues of the knee underlying the patella. If desired, the inductor coil may be of elliptical or elongate from in the direction transversely of the knee so as to provide enhanced therapy for patella tendon disorders The power module

86 for energising the coil is appropriately secured to the front surface of the knee brace below the patella opening 256.

The orthotic device illustrated in Figures 27 and 28 is designed for the treatment and rehabilitation of lumbo sacral soft tissue pain syndromes.

Lower back pain is the most common musculo skeletal symptom experienced by human beings. In the majority of cases there is no demonstrable disk or boney pathology and thus the exact nature of the underlying pathology is not clearly definable. The vast majority of cases present clinically an array of pain syndromes with associated restriction of movement. The pain is predominantly in the lumbo sacral region dorsally, although it can radiate into the buttocks or proximal thigh. Any or all movement of the lumbo sacral spine are restricted.

There is a vast array of treatments, modalities and methods used to treat these conditions. The most common include the use of anti-inflammatory drugs, manipulative therapies, exercise regimes and lumbo sacral braces.

Inasmuch as conventional lumbo sacral orthoses are used to augment the supporting musculature of the lumbo sacral spine and to provide pain relief by limiting exacerbating movements, the incorporation of PEMFT in the orthoses will significantly enhance the therapeutic benefits available with the orthoses.

As shown in Figure 27. an anatomically designed and shaped, front securing, lumbo sacral orthotic device 270 having a body portion 272 designed for application to the waist region of the user, is preferably comprised of heat retentive flexible material. In the embodiment illustrated, the orthotic device is adopted to be wrapped about the waist of the user and secured at the front by velcro material 274.

Referring to Figure 28, a PEMF therapy module 80 and associated inductor(s) is secured to the orthotic body 272 so as to be positioned over the lumbo sacral region of the user. The design of the enhanced lumbo sacral orthotic device is such that comfortable fit is only possible when worn in accordance with the designer's instruction, and in this way, the electromagnetic fields will be aligned and positioned correctly over the lumbo sacral tissues requiring therapy.

The orthotic device of Figures 29, 30 and 31 is intended for the treatment and rehabilitation of soft tissue pain syndromes of the shoulder.

It is generally understood that soft tissue pain syndromes of the shoulder have varied and poorly defined underlying pathologies. Such conditions generally involve overuse injuries of the tendons at the musculo tendinous junction as well as various trauma injuries to the collagen fibres within the tendons of the shoulder.

While the underlying pathology may be variable, the pain syndromes associated with these conditions usually include shoulder stiffness, pain on movement, restricted mobility and crepitus, and can be extremely debilitating in many sufferers.

Soft tissue pain syndromes of the shoulder are usually treated with a variety of therapies including the application of anti-inflammatory medications, the use of certain immobilisation aids and various physical therapy means. Less common is the application of acupuncture, ultrasound and interferential therapy.

Soft tissue pain syndromes of the shoulder are notoriously difficult to treat using such therapies. Efficacies of less than 30% are commonly encountered. This is primarily due to the fact that such traditional therapies are designed to modify the pain and

discomfort issues associated with these conditions andthere is currently little scientific evidence that such therapy means modify or alter the underlying pathology present.

Referring to Figure 29-31, there is provided an anatomically designed and shaped orthotic device 290 having a body portion 292 suitable for application to the shoulder region of a user and comprising double lined neoprene type heat retentive material, pectoral and scapula panels 294, and elastic securing straps 296. A pulsed electromagnetic field module 80 is attached to the body of the orthotic device by insertion into a pocket or sleeve prior to being sewn closed. Power receptor plug is provided for the connection of direct current voltage from an external source.

Figure 29 and 30 are front and rear views, respectively, of the orthotic when positioned over the shoulder of the user and provided with a ELF-PEMFT module for treatment of the shoulder joint.

Figure 31 shows the same orthotic device, but with pulsed electromagnetic field module 86 affixed to the pectoral panel 274 in the case where therapy is required to be administered to the tendons of the front breast area. Similarly, a PEMFT module may be mounted on the scapula panel (not illustrated) in the case where therapy is required to be applied to the back.

The elastic securing straps and pectoral and scapular panels provide for improved comfort and positional stability. The heat retentive flexible material provides for increased metabolism, overall activity modification and enhanced proprioception. Thus, in addition to therapeutic electromagnetic field therapy, the orthotic provides a variety of therapeutic effects directly over the affected tendon region.

Figures 32 and 33 illustrate a very similar shoulder orthotic device which, in the present instance, is intended for the treatment and rehabilitation of supraspinatus tendinitis and other rotator cuff pain syndromes.

It is generally understood that suspraspinatus tendinitis and other rotator cuff pain syndromes involve inflammation of the tendons of the supraspinatus muscles and those of the other muscles contributing to the rotator cuff. The tendons become inflamed and abduction of the arm is limited.

Suspraspinatus tendinitis and other rotator cuff pain syndromes are common causes of pain syndromes in adults and can be very disabling. Therapy can involve direct injections of corticosteroids, physiotherapy and the use of anti-inflammatory medications. These modalities have historically only been effective in a limited number of cases and more convervative therapies have been found to be of limited and unproven benefit.

Partial disruption of the blood supply to the tendon by over use and compression of the vessels against the acromion is thought to be imnportant in initiating the disorder. This can render the tendon liable to damage from trivia or often unrecognised trauma. Since the vasccular supply to the adult supraspinatus tendon is normally poor, healing of the lesions can be extremely slow.

Figures 32 and 33 are, respectively, from and rear views of a shoulder orthotic device 320 having a body 322 formed of flexible, heat retentive material conformable to the shoulder regions of the wearer and preferably though not necessarily including pectoral and scapular panels 324 and elastic securing straps 326. In this instance, the PEMFT module 80 is so shaped and sized as to administer highly efficacious extremely low frequency electromagnetic field therapy to the supraspinatus tendon and the rotator cuff.

Figures 34 and 35 are front and rear views, respectively, of a neck and shoulder orthotic for the treatment and rehabilitation of soft tissue cervical spine pain syndrome.

It is generally understood that soft tissue injuries of the cervical spine produce pain syndromes and neck stiffness. The exact nature of the underlying pathology is rarely definable. It is generally accepted that there is likely to be inflammation of the soft tissue structures supporting the cervical spine. The pain syndromes are variable but generally have associated neck stiffness, pain on movement of the cervical spine, and radiation of pain across the top of the shoulders. These syndromes are distinct from those associated with cervical nerve root compression or irritation. They are also distinct from pain syndromes associated with cervical disk disease.

These soft tissue related pain syndromes are currently treated by a variety of treatments modalities and methods. The most common are the use of anti-inflammatory drugs and physical therapy. These are primarily aimed at pain control and restoration of range of motion. Less common modalities include acupuncture, ultrasound and interferential therapy. There is currently little scientific evidence to support a claim that such therapy acts directly to effect the underlying pathology of this disorder.

Referring to Figures 34-35, there is provided an anatomically designed and shaped orthotic device 340, suitable for application to the cervical spine region and neck, comprising flexible heat retentive material. The orthotic may be secured and held positionally stable by means of velcro or other similar materials that serve to affix one end of the orthotic to the other end as is conventional for cervical collars. A pulsed electromagnetic field module may be attached

or integrated into the orthotic proper in any appropriate or desired manner. For example, an inductor 84 may be secured to the rear surface of the orthotic and a driver module 86 may be positioned on the front of the orthotic for ease of access to the receptor plug. Although the exact design and location may vary, the purpose of the pulsed electromagnetic field module is to supply pre-shaped electrical current waveforms to inductor/s that have previously been integrated into the orthotic to administer PEMF therapy to the desired regions of the neck and upper back.

The orthotic device of Figure 36 is designed for the treatment and rehabilitation of overuse injuries of the lateral epicondyl and other epicondyl disorders.

It is generally understood that the condition known as tennis elbow or laterial epicondylitis involves inflammation of the tendons of the extensor forearm muscles at the point where they attach to the bony prominence of the outer side of the elbow. The condition develops as the result of overuse with inflammation resulting from devitalisation and disruption of the tendon fascicles caused by repetitive microtrauma. Continuing overuse and the resulting secondary inflammation reaction can produce an overload immature scar that may worsen the lesion. Repeated microtrauma may produce an area of degeneration with inflammation and central necrosis that may act as an ongoing irritative focus and lead to tendon rupture. The symptoms are inflammation, swelling, tenderness, pain, induration and crepitus.

Effective therapy for lateral epicondylitis can include compression, support, selective immobilisation and activity modification. Pulsed electromagnetic field therapy has been clinically proven to provide significant pro-healing benefits, especially in disorders of the tendon sheath, and when such fields

are propagated into the tissues under treatment with correct orientation and alignment, cause specific biological changes that result in accelerated healing, reduced inflammation and rapid tissue regeneration.

As shown in Figure 36, an orthotic device 360 for PEMF treatment of tennis elbow and other disorders of the lateral epicondyl is comprised of an elbow embracing body portion 362, preferably formed from a flexible heat retentive material, a PEMFT module 80 (suitably of the Figure 4 - Figure 8 embodiment) permanently affixed to the body 362 for correct orientation of the inductor relative to the lateral epicondyl, and a compression strap 364 with associated buckle 366 for holding the module 80 securely in place. The compression strap provides positional stability, and is adjustable to provide as well for selective immobilisation and activity modification. The body 362 is provided with an olecranon cutout 368 for positional stability and increased freedom of flexation, while readily indicating incorrect fit or anatomical misalignment. The use of double lined heat retentive flexible neoprene type material for the body provides for increased metabolism, overall elbow activity modification and enhanced proprioception for the avoidance of additional injury.

The orthotic device of Figure 37 is designed for the treatment and rehabilitation of overuse injuries of the medial epicondyl and other medial epicondyl disorders.

It is generally understood that the condition known as golfer's elbow or medial epicondylitis involves inflammation of the tendons of the flexor forearm muscles at the point where they attach to the bony prominence of the medial or inner side of the elbow. The condition develops as the result of overuse with inflammation resulting from devitalisation and

disruption of the tendon fascicles caused by repetitive microtrauma.

Continuing overuse and the resulting secondary inflammation reaction can produce an overload immature scar that may worsen the lesion. Repeated microtrauma may produce an area of degeneration with inflammation and central necrosis that may lead to tendon rupture. The symptoms are the classical ones of any inflammation, including swelling, tenderness, pain, induration and crepitus.

As with lateral epicondylitis, effective therapy for medial epicondylitis should include compression, support, selective immobilisation and activity modification.

As shown in Figure 37, the device 370 provided by the invention for treatment of medial epicondylitis is essentially the same as the device provided for treatment of lateral epicondylitis, except that the EMF inductor is focused on the medial epicondyl. Specifically, the device 370 comprises an elbow embracing body heat retentive orthotic body member 372, an olecranon cutout 378 in the body for accuracy of alignment and positional stability, a PEMFT module 80 permanently affixed to the body for proper orientation of the inductor relative to the medial epicondyl, and a compression strap 374 with associated buckle 376 for application of variable pressure for purposes of positional stability and selective immobilisation.

The orthotic device illustrated in Figure 38 is a wrist and arm orthotic for the treatment and rehabilitation of soft tissue wrist pathologies.

The device comprises an anatomically designed lightweight orthotic that encompasses the wrist and lower arm and incorporates therapeutic pulsed electromatnetic field means affixed at a location that assures accurate theraeutic field alignment, location

and orientation for effective therapy of soft tissue wrist pathologies.

Soft tissue injuries about the wrist include capsular strain, intercarpal ligament strain, and extensor tendinitis. They are characterised by pain and restricted movement which persists despite an absence of boney pathology in the region. Such injuries often lead to persistent symptoms and associated disablement.

These soft tissue injuries are generally treated by a variety of treatments, modalities and methods. The most common include the administration of anti-inflammatory drugs, the use of a wrist splint to limit movement and reduce pain, and various physical therapy techniques. There is little scientific evidence to demonstrate the efficacy of these existing modalities and methods with respect to altering the underlying pathology. Clinical trials and cellular research projects have however established the efficacy of PEMF in respect of relief of pain and improved range of motion in many disorders with underlying pathology similar to those encountered in soft tissue wrist syndrome.

Referring to Figure 38, there is provided an anatomically designed and shaped orthotic device 380, designed for application to the wrist and lower arm region. The device comprises a wrist and lower arm embracing body 382 preferably comprising double lined neoprene type heat retentive material. Thumb hole 384 provides both positive fit and positional stability. The orthotic may if desired be supplied with a compression band (not illustrated) for additional therapeutic benefit. Pulsed electromagnetic field module 80 may be attached to or integrated into the body 382. Although the exact design and location may vary, the purpose of the pulsed electromagnetic field

module 80 is to supply the required current to the inductor/s which are placed over the region of the wrist desired to be treated. In the illustrated embodiment, the inductor is placed over the dorsal surface of the wrist central to the joint line.

In the foregoing description, it has been presumed that, for purposes of economical manufacture, consumer acceptance and convenience of use, it would be desirable to provide to the consumer a totally self-contained orthotic device comprised of orthotic, inductor and waveform generation, requiring only the connection to a D.C. source of proper voltage. Alternatively, a variety of self-contained envelopes each consisting of an inductor and waveform generator, could be provided to health care professionals for affixation of a selected module to a selected orthotic in order to administer to a patient a specific therapy prescribed by the health-care professional.

However, as the industry continues to mature, it appears that a forthcoming trend will be to provide machine controlled administration of the therapy in order to record the time at which the therapy is administered, the duration of the treatment and the specific waveform utilized, thereby to insure that a patient is adhering religiously to the therapeutic regimine prescribed. Also, it is contemplated that some form of credit card or like system may be utilized in conjunction with the machine control to provide for instant payment or computerized billing for each therapy session. In this environment, it would appear impractical to incorporate the waveform generator in the orthotic device, since it could far more conveniently and practically be incorporated in the therapy controlling and recording apparatus.

Figure 39 provides a schematic illustration of the arrangement contemplated. For purposes of illustration there is shown an orthotic similar to or the same as the orthotic 230 of Figures 23-24. The orthotic, indicated at 390, is comprised of a knee encircling brace or sleeve 392 have patella opening 394 for positional alignment and stability. An inductor 396 is affixed to the orthotic in essentially concentric relation to the patella opening as in Figures 23-24. In this case, the unit 396 is simply an inductor coil having a power connector 398 adjacent its marginal edge.

A control module 400 incorporates all of the circuitry (including the waveform generator) required to control, administer and record the therapy administered to a given patient. A patient identity card receptacle 402 is provided. In order to receive therapy, the patient simply connects the coil 396 of her or his orthotic device to the control module via connector cable 404, inserts the personal patient ID card into the slot 402 and pushes a start button, whereupon the therapy is administered and recorded under the control of the module 400. A built-in timer signals the conclusion of the treatment.

The modified arrangement of Figure 39 can of course be used for energization and control of any or all of the orthotics devices illustrated in Figures 9 to 38. The orthotic devices themselves remain viable in all instances for ELF-PEMFT treatment of the specific disorders for which designed.

Thus the objects and advantages of the present invention have been shown to be attained in a convenient, economical and practical manner.

While a wide variety of preferred embodiments of the invention have been herein illustrated and described, it is to be appreciated that various changes, rearrangements and modifications may be made therein without departing from the scope of the invention as defined by the appended claims.

CLAIMS

1. A disorder specific orthotic device incorporating pulsed electromagnetic field therapy comprising an orthotic anatomically designed to have a proper fit on a specific body region, limb or joint and to have only one position in which the fit is comfortable, an extremely low frequency pulsed electromagnetic field inductor permanently positioned on the orthotic in the proper position to generate and administer extremely low frequency pulsed electromagnetic field therapy to specific body tissues in such region, limb or joint for proper treatment of a specific disorder, and a D.C. power supply and wave form generator electrically connected to said inductor for energizing the same.

2. An orthotic device as set forth in Claim 1 wherein the orthotic includes means for assuring one and only one position of comfortable fit.

3. An orthotic device as set forth in Claim 2 wherein the orthotic includes means for snugly engaging a bodily protuberance contiguous to the body region, limb or joint to which the orthotic is fitted.

4. An orthotic device as set forth in Claim 1, 2 or 3 wherein the orthotic is a wearable orthotic permitting ambulatory movement.

5. An orthotic device as set forth in any of the preceding claims wherein the orthotic is designed and made from a heat-retentive, body hugging material.

6. An orthotic device as set forth in Claim 5 wherein the material is a double-lined neoprene type of material.

7. An orthotic device as set forth in Claim 1, wherein the D.C. power supply and waveform generator are separate and physically displaced from the orthotic.

8. An orthotic device as set forth in Claim 1, wherein the D.C. power supply and waveform generator are mounted on the orthotic in a comfortable and convenient location near said inductor.

9. An orthotic device as set forth in Claim 1, wherein said inductor and said D.C. power supply and waveform generator are combined into a single module and positioned as a unit on said orthotic.

10. An orthotic device as set forth in Claim 1 wherein said inductor is encapsulated in a protective cover and the cover is affixed to the orthotic.

11. An orthotic device as set forth in Claim 8, wherein said inductor and said D.C. power supply and waveform generator are each individually encapsulated in a protective cover and the two covers are individually affixed to the orthotic.

12. An orthotic device as set forth in Claim 9, wherein said inductor and said D.C. power supply and waveform generator are encapsulated within a common protective cover and the cover is affixed to the orthotic.

13. An orthotic device as set forth in any of the preceding claims designed for ELF-PEMF therapy of plantar fascitis comprising an ankle and foot encompassing orthotic having a heel cutout and ELF-PEMF inductor means positioned on the orthotic under the plantar fascitis of the foot.

14. An orthotic device as set forth in any of the preceding claims designed for ELF-PEMF therapy of achilles tendinitis comprising an ankle and foot encompassing orthotic having a heel cutout and ELF-PEMF inductor means positioned on the orthotic over the region of the achilles tendon.

15. An orthotic device as set forth in any of the preceding claims designed for ELF-PEMF therapy of inversion injuries and other disorders of the ankle comprising an ankle and foot encompassing orthotic having a heel cutout and ELF-PEMF inductor means positioned on the orthotic over the medial, lateral and/or anterior regions of the ankle.

16. An orthotic device as set forth in any of the preceding claims designed for ELF-PEMF therapy of achilles tendon musculotendinous comprising a calf orthotic snugly embracing the calf and ELF-PEMF inductor means positioned on the orthotic over the gastrocnemius/achilles tendon musculotendinous junction.

17. An orthotic device as set forth in any of the preceding claims designed for ELF-PEMF therapy of fractures and other injuries to the tibia comprising a a calf orthotic snugly embracing the calf and tibial regions of the leg and ELF-PEMF inductor means positioned on the orthotic on opposite sides of and parallel to the tibia.

18. An orthotic device as set forth in any of the preceding claims designed for ELF-PEMF therapy of injuries to the hamstring and quadriceps muscle groups comprising an orthotic snugly encircling the thigh and ELF-PEMF inductor means positioned on the orthotic in overlying relation to the hamstring and quadriceps muscle groups.

19. An orthotic device as set forth in any of the preceding claims designed for ELF-PEMF therapy of soft tissue injuries of the groin comprising a snug fitting pair of shorts and ELF-PEMF inductor means positioned on the shorts in overlying relation to the regions of the groin.

20. An orthotic device as set forth in any of the preceding claims designed for ELF-PEMF therapy of knee joint and patellar type injuries comprising an orthotic knee brace having a patella opening and ELF-PEMF inductor means positioned on the orthotic (1) on the medial and/or lateral sides and/or the anterior surface of the knee or (2) on the anterior surface of the knee generally concentric to the patella or (3) on the anterior surface of the knee below the patella.

21. An orthotic device as set forth in any of the preceding claims designed for ELF-PEMF therapy of lumbo sacral soft tissue pain syndrome comprising a waist and back encircling orthotic and ELF-PEMF inductor means positioned on the back of the orthotic in overlying relation to the lumbo sacral region.

22. An orthotic device as set forth in any of the preceding claims designed for ELF-PEMF therapy of soft tissue pain syndromes of the shoulder and rotator cuff comprising a shoulder orthotic overlying the shoulder and upper arm and having pectoral and scapula panels and ELF-PEMF inductor means positioned on the orthotic (1) in overlying relation to the shoulder joint or (2) on the pectoral panel or (3) on the scapula panel.

23. An orthotic device as set forth in any of the preceding claims designed for ELF-PEMF therapy of soft tissue cervical spine pain syndromes comprising a neck and upper back embracing orthotic and ELF-PEMF inductor means positioned on the back of the orthotic in overlying relation to the neck and the upper spine.

24. An orthotic device as set forth in any of the preceding claims designed for ELF-PEMF therapy of epicondylitis comprising an elbow encircling orthotic having an olecranon opening and ELF-PEMF inductor means positioned on the orthotic to overlie (1) the lateral epicondyl or (2) the medial epicondyl.

25. An orthotic device as set forth in any of the preceding claims designed for ELF-PEMF therapy of soft tissue wrist pathologies comprising a wrist, hand and lower arm embracing orthotic having a thumb opening and ELF-PEMF inductor means positioned on the orthotic in a location to treat a specific wrist or forearm pathology.

Fig 1.

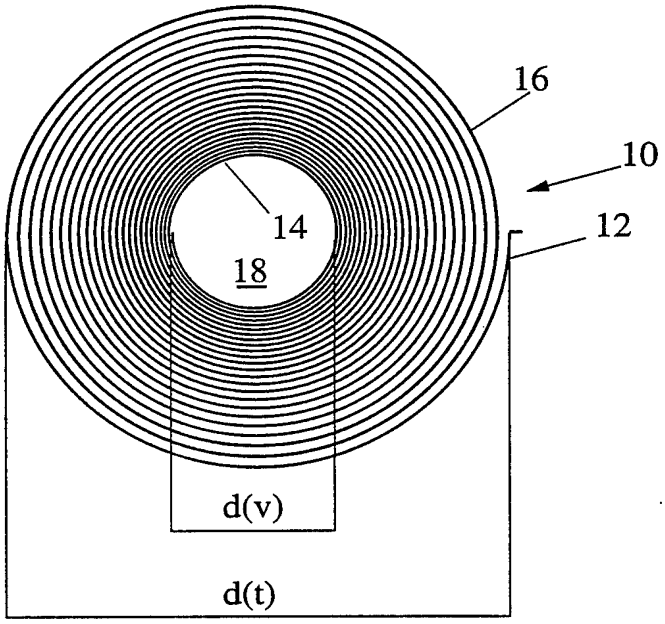
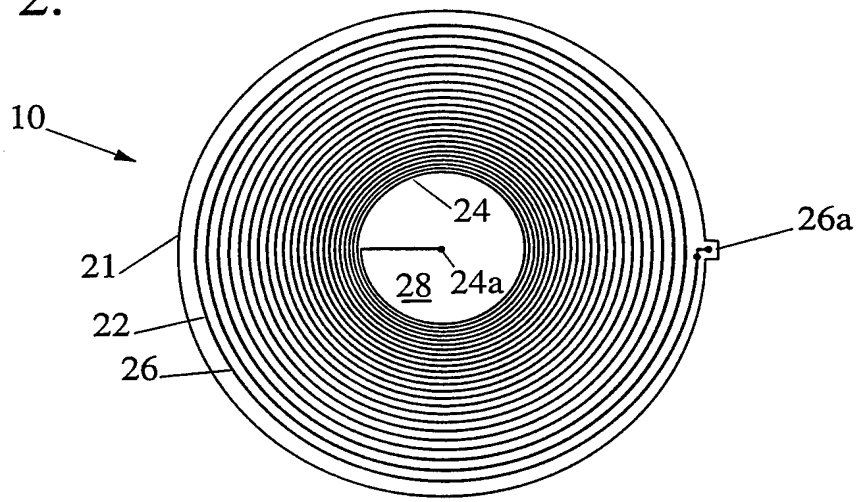


Fig 2.



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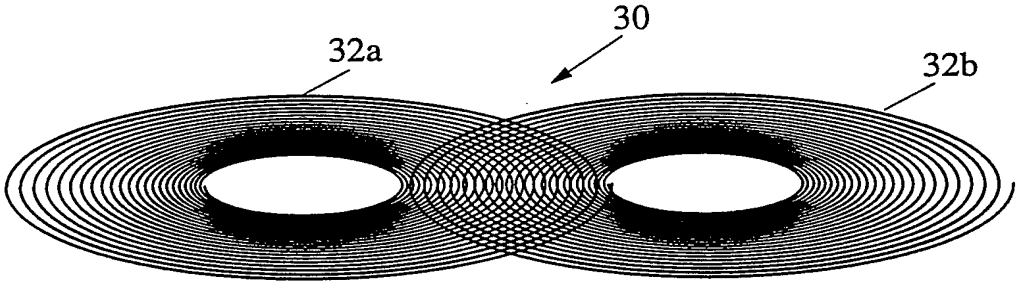

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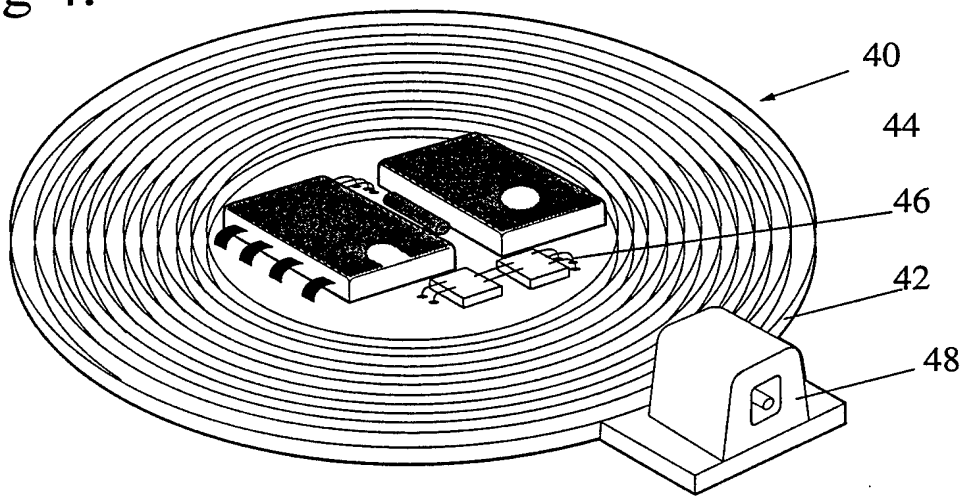
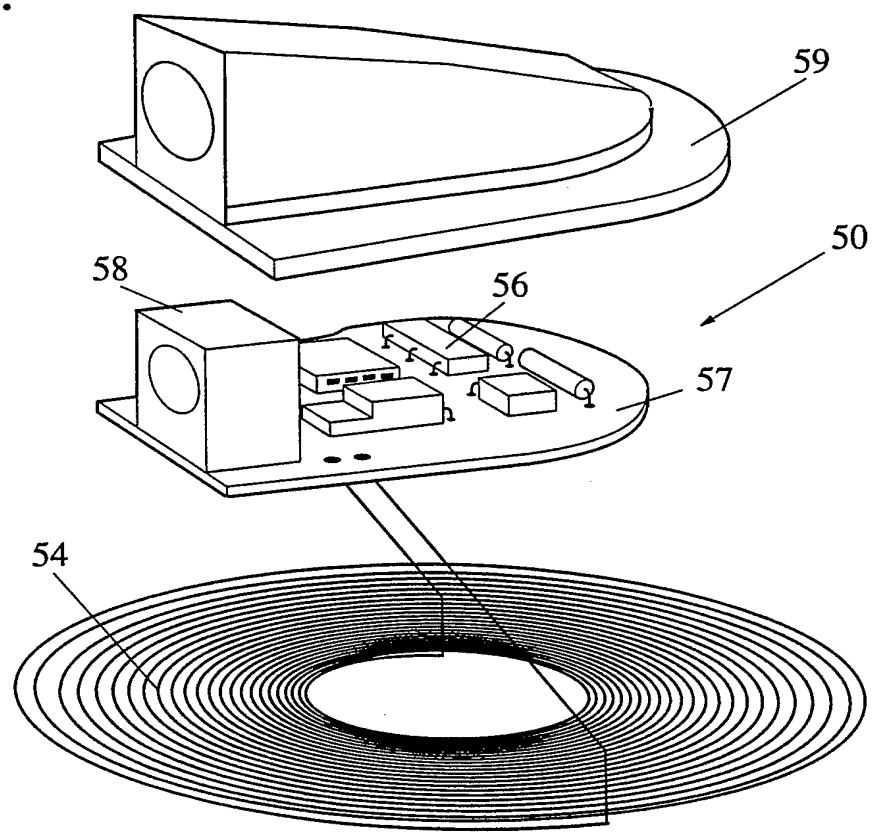


Fig 5.



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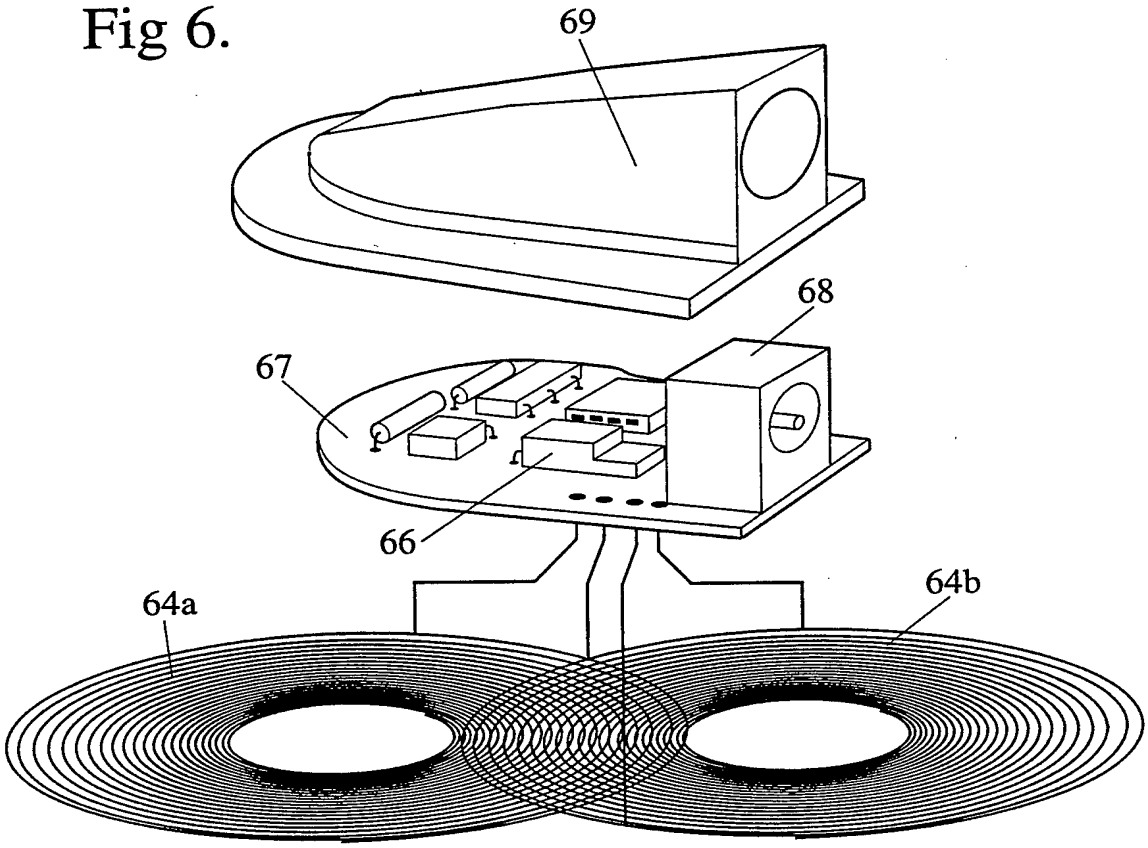

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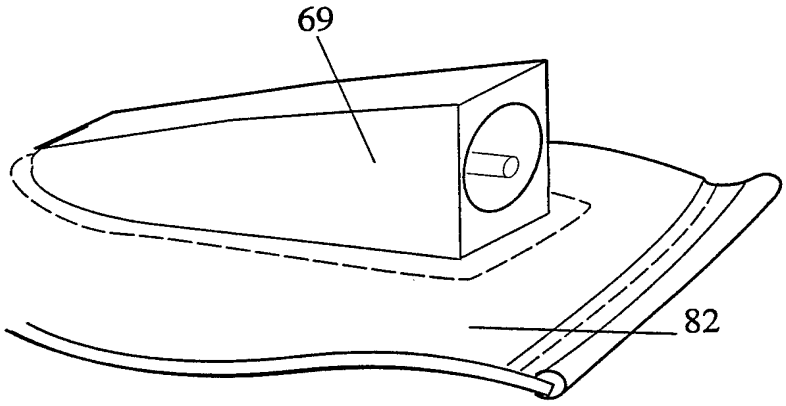

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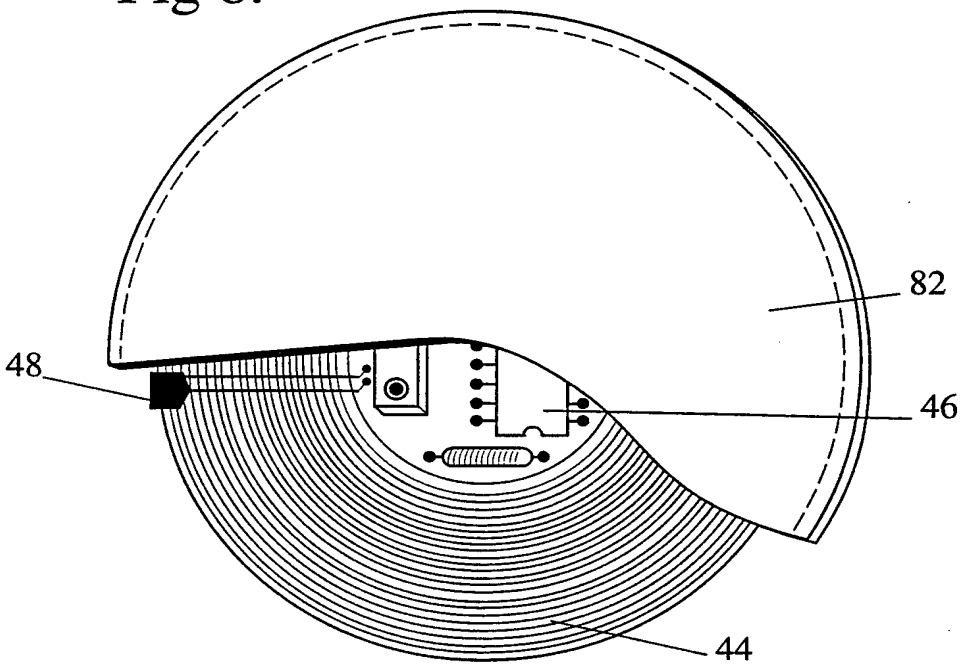

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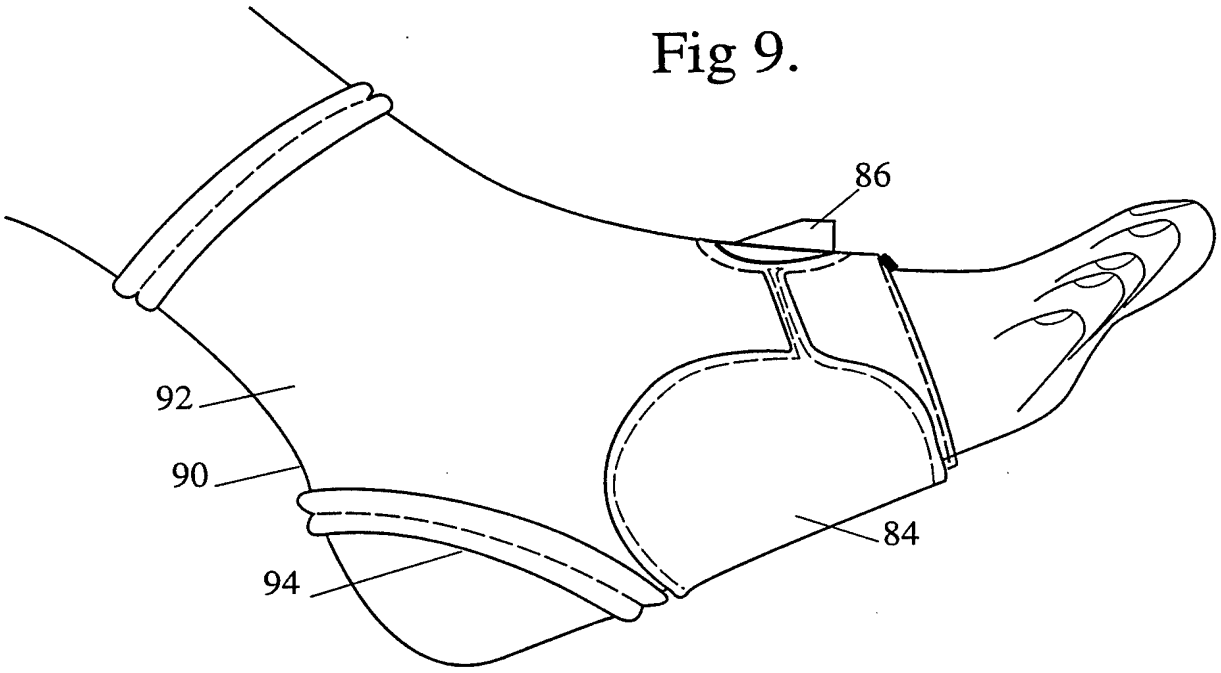

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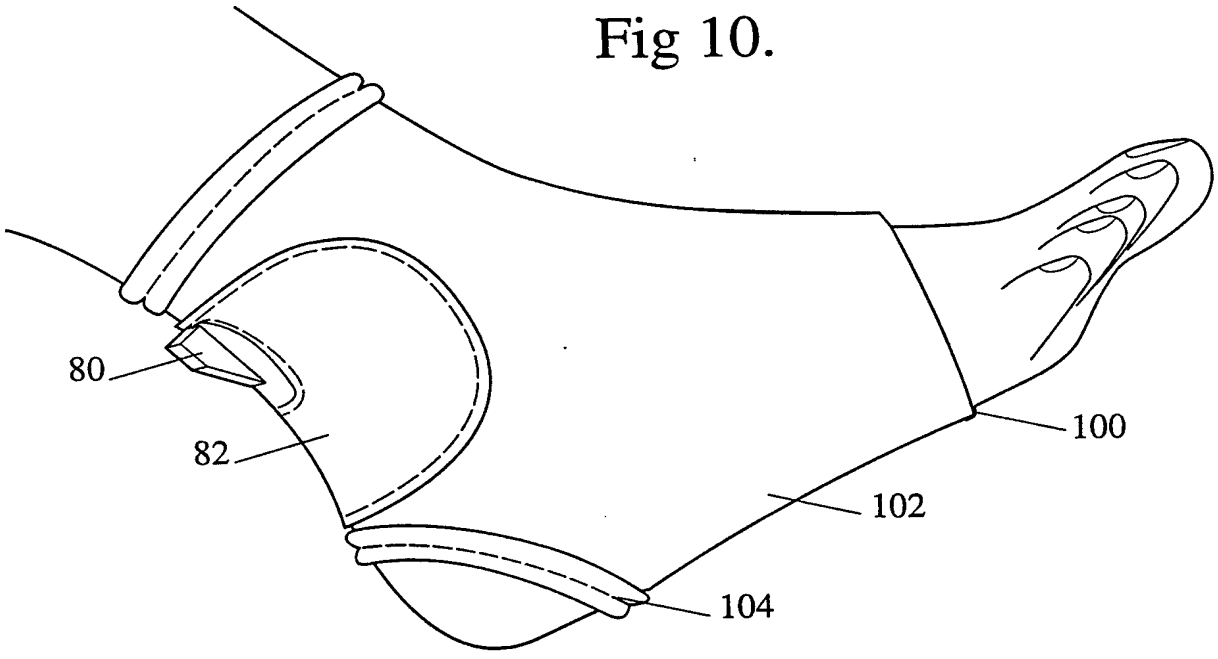

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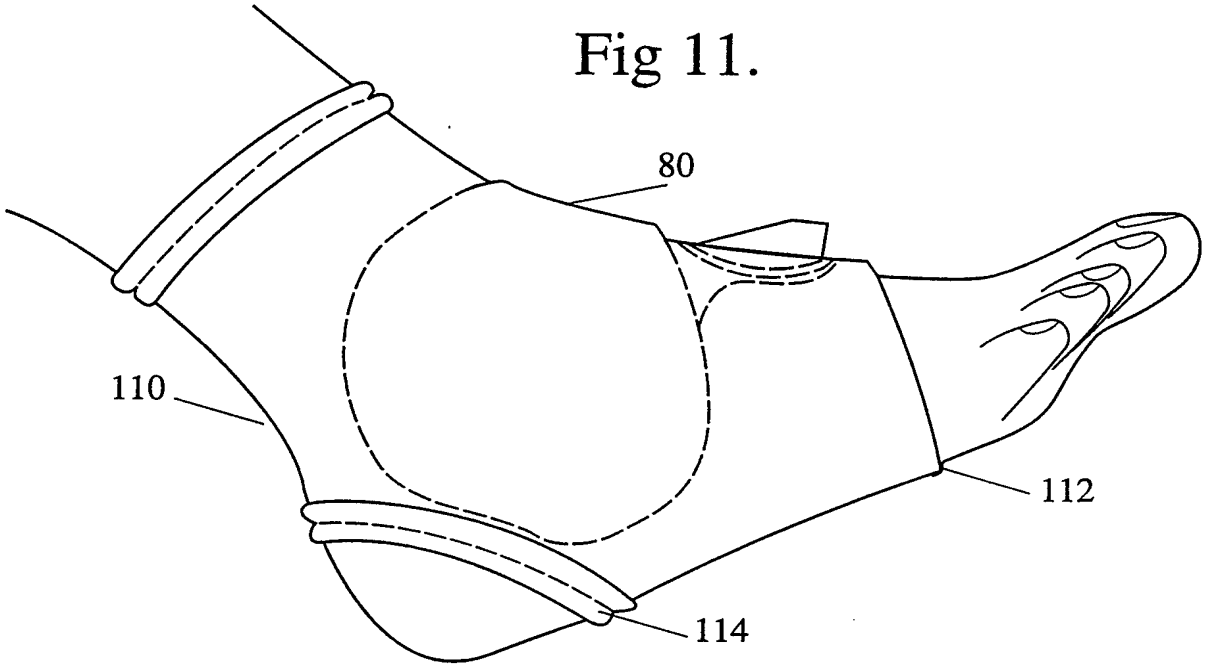

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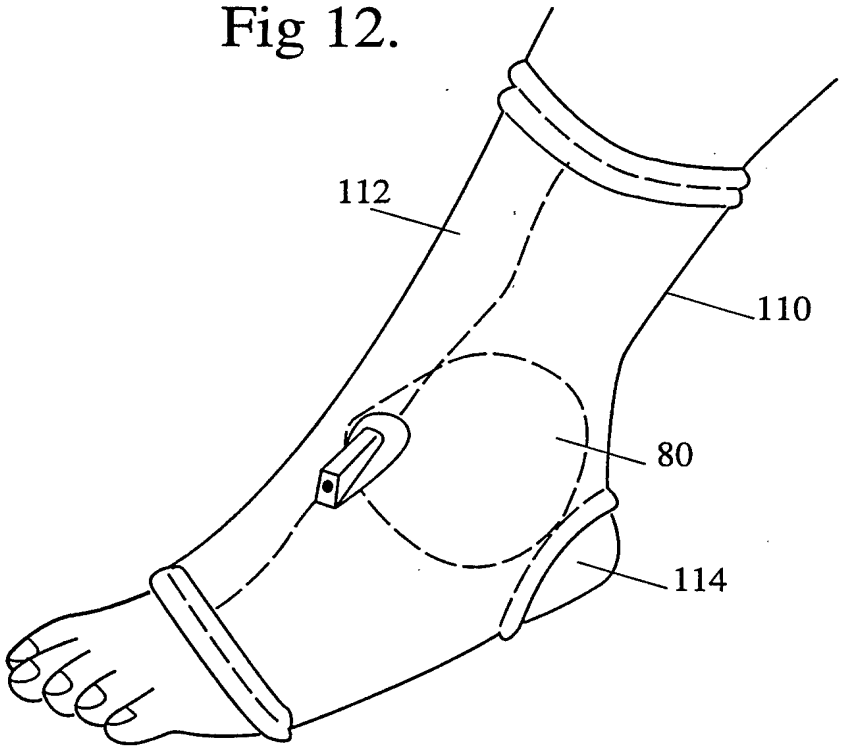


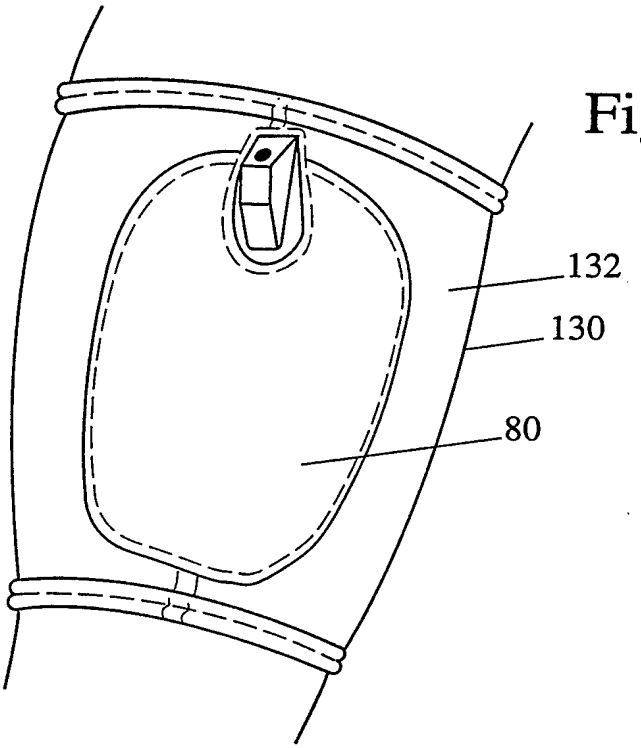
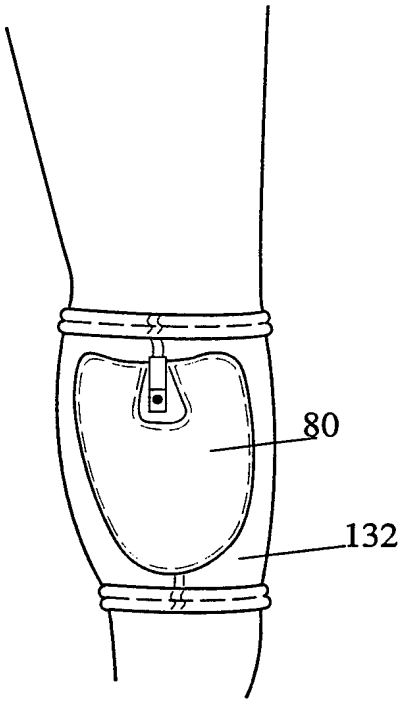


Fig 13.

Fig 14.



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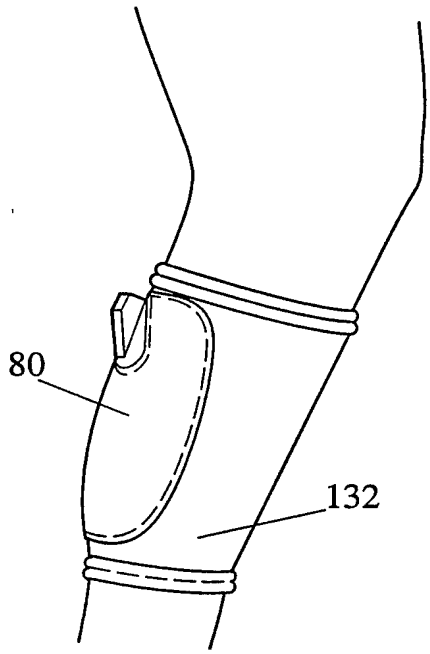

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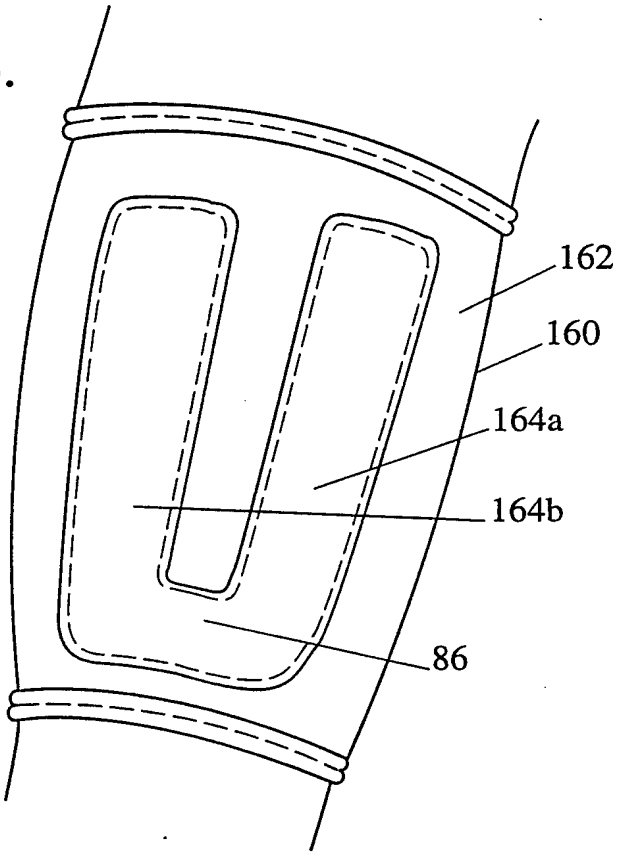

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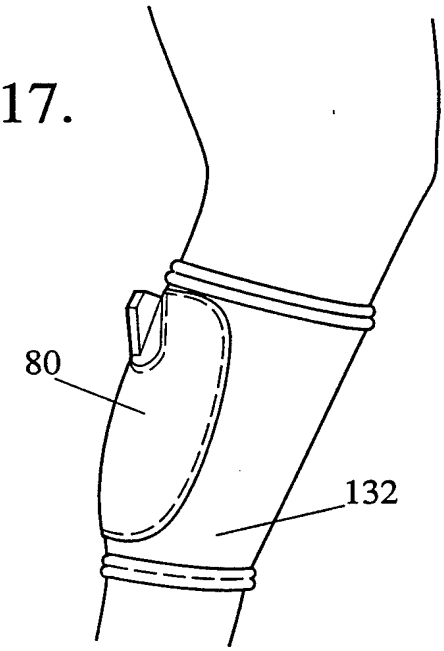

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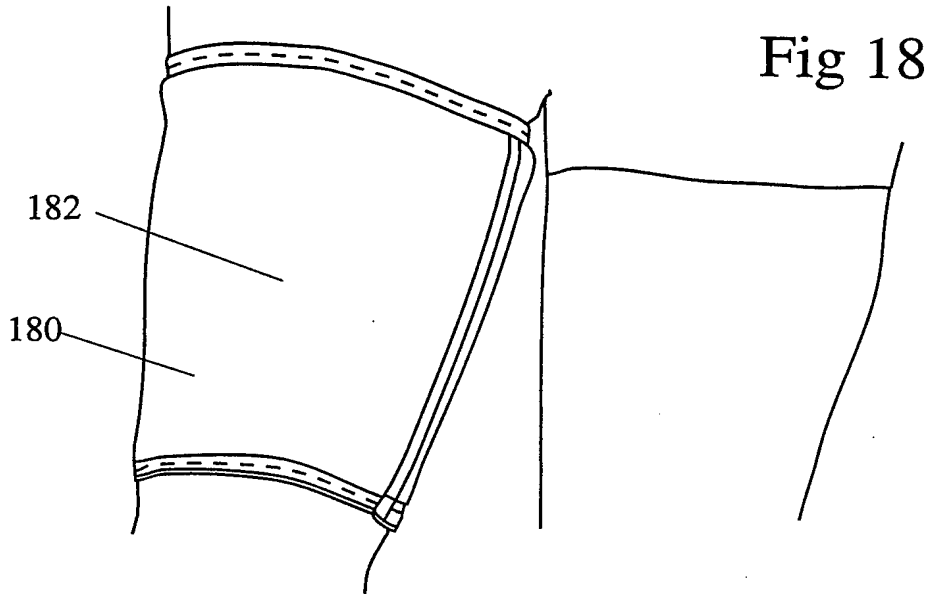

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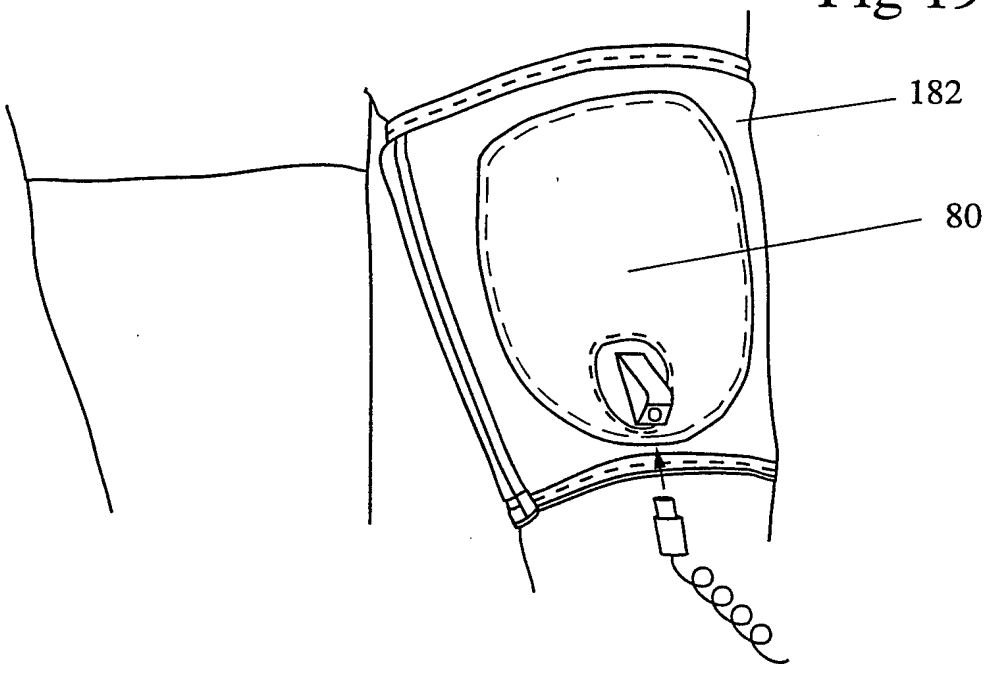

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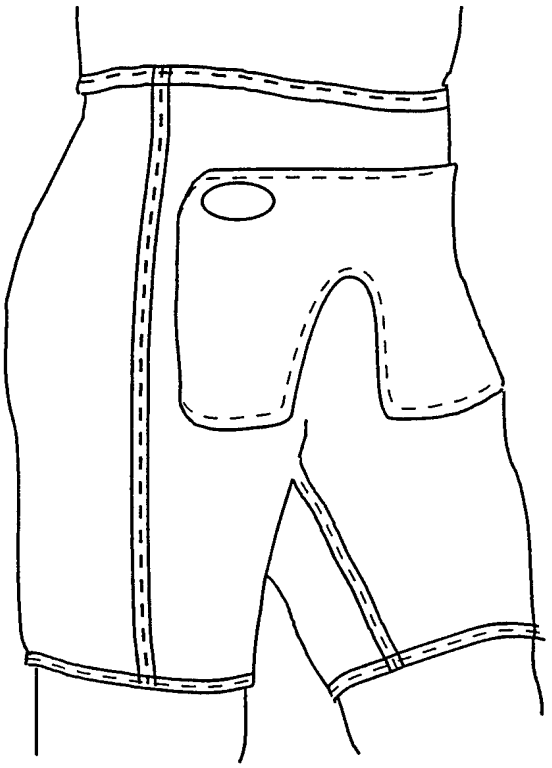

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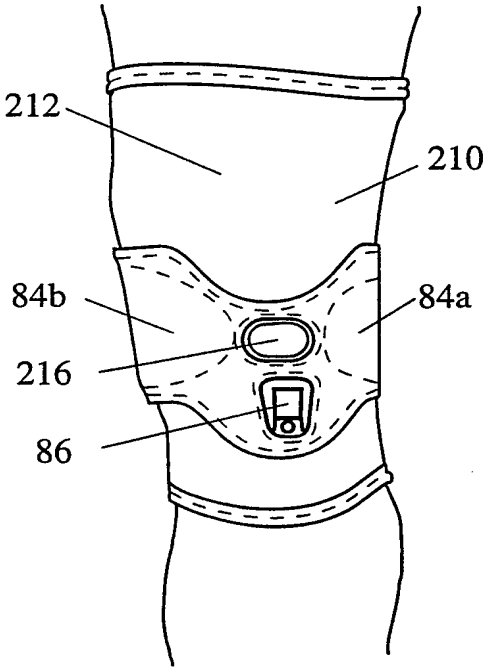

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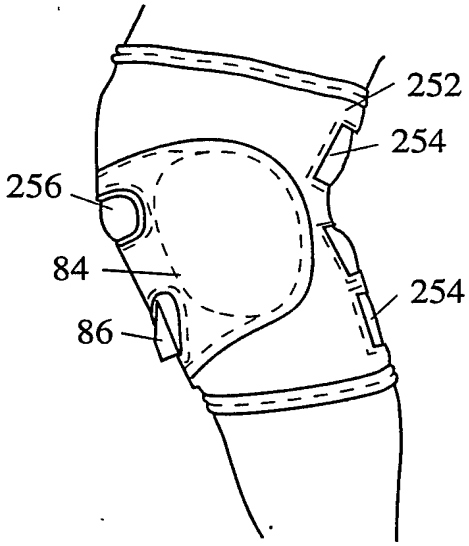

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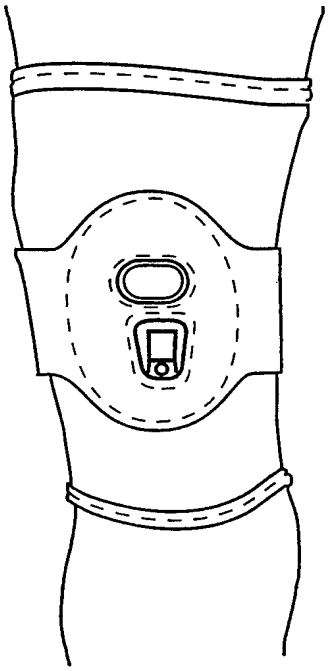

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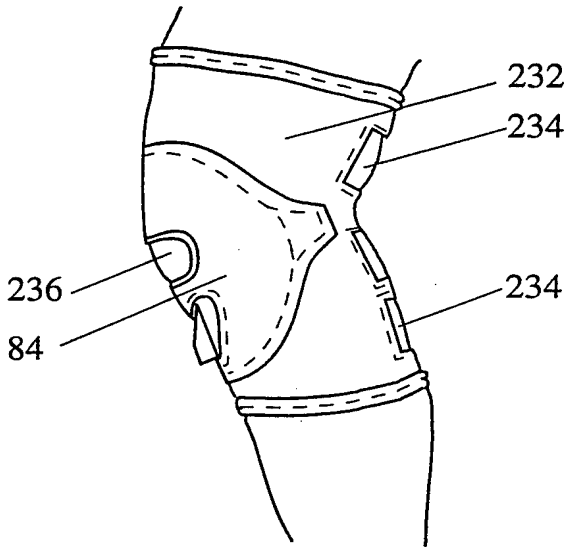

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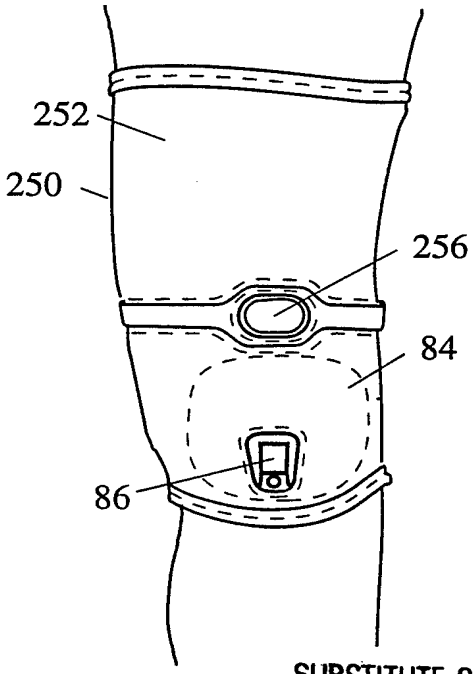

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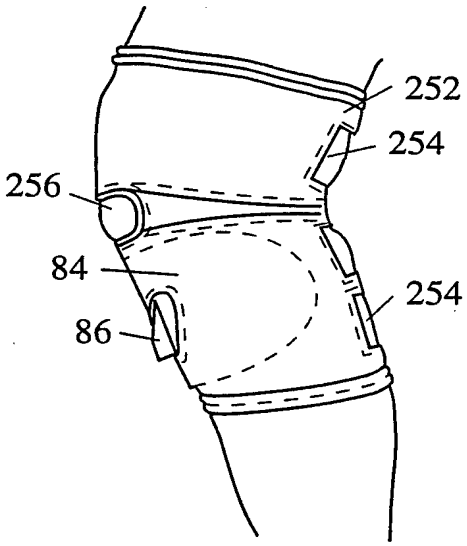

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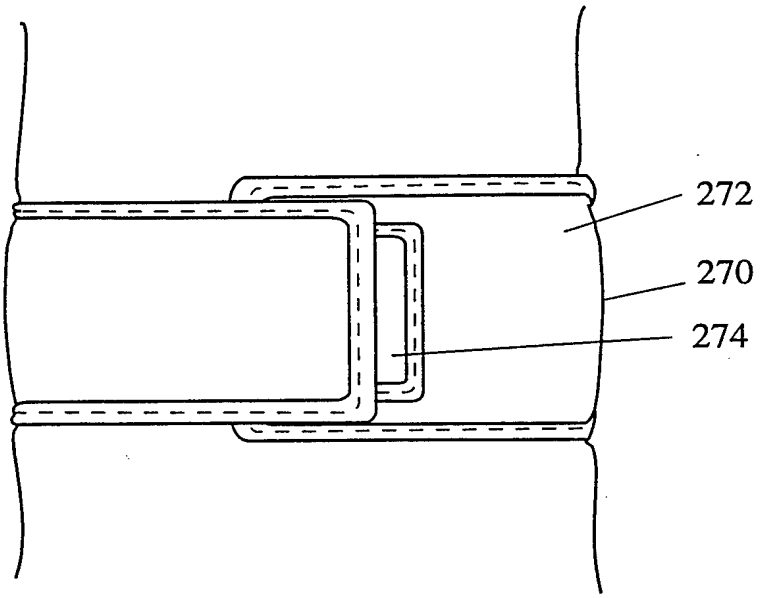

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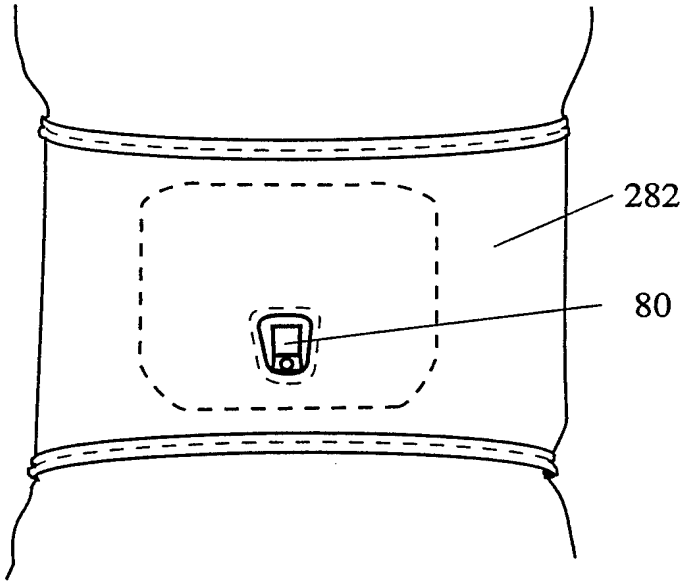

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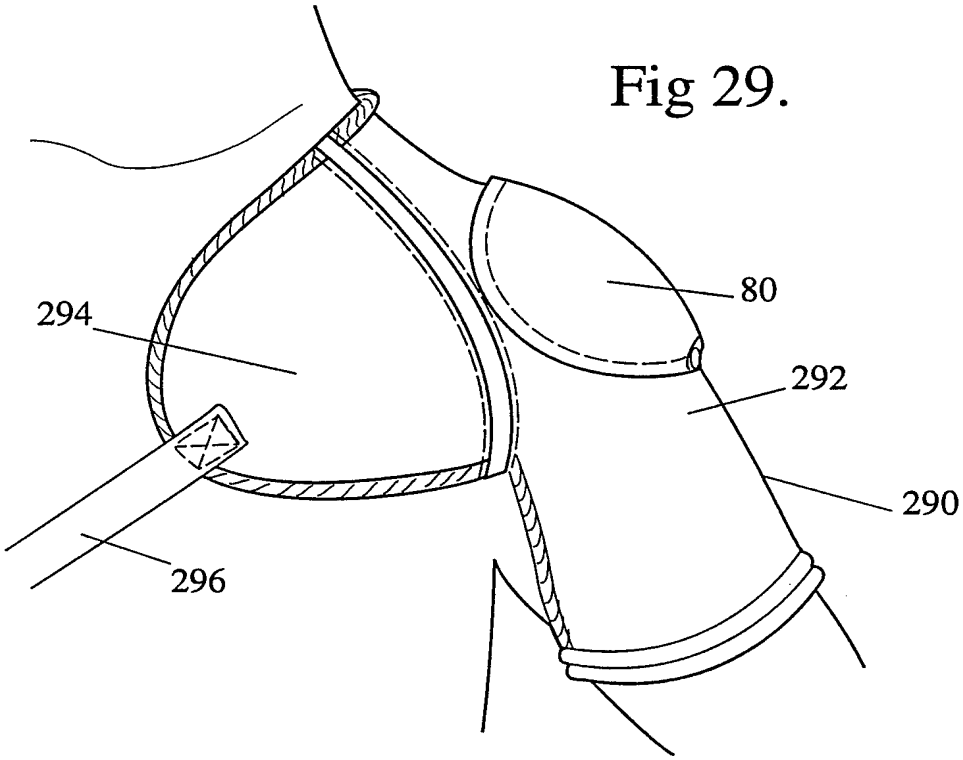

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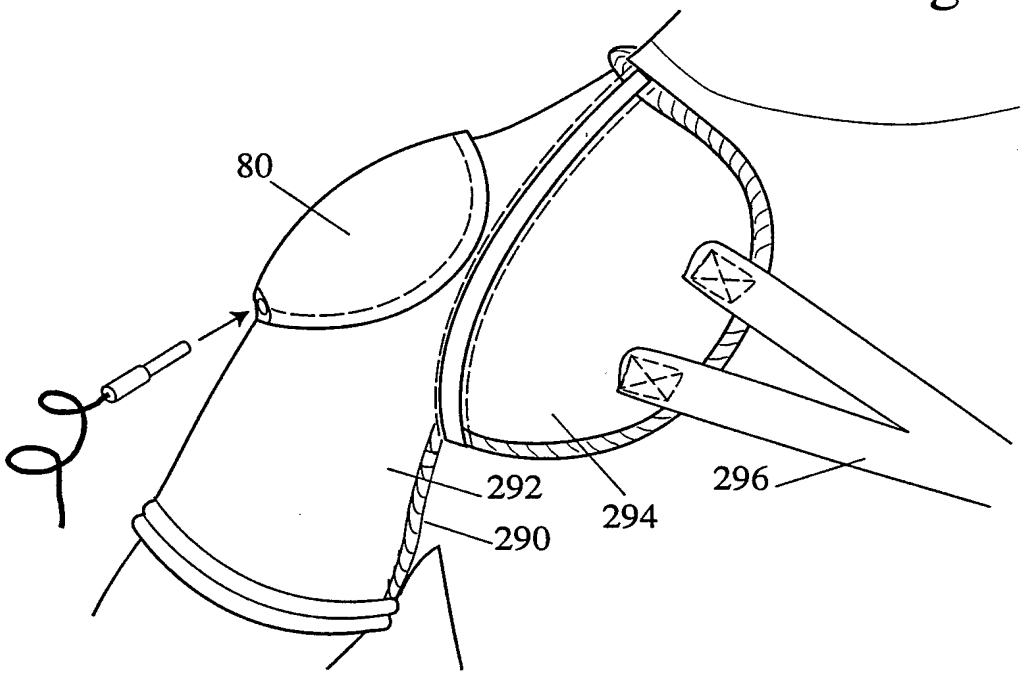

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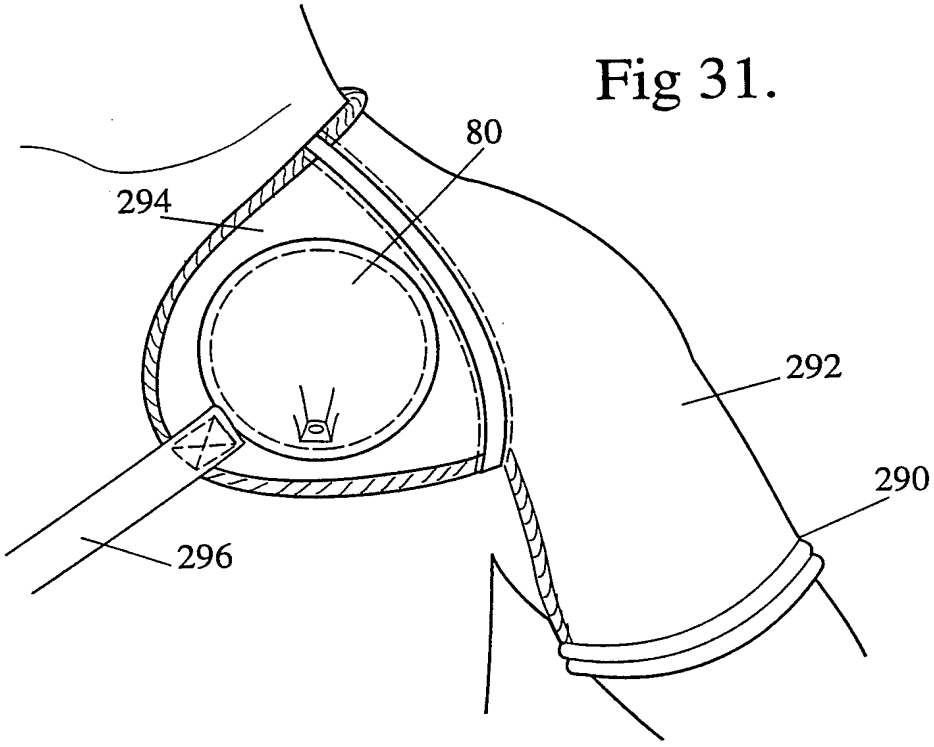

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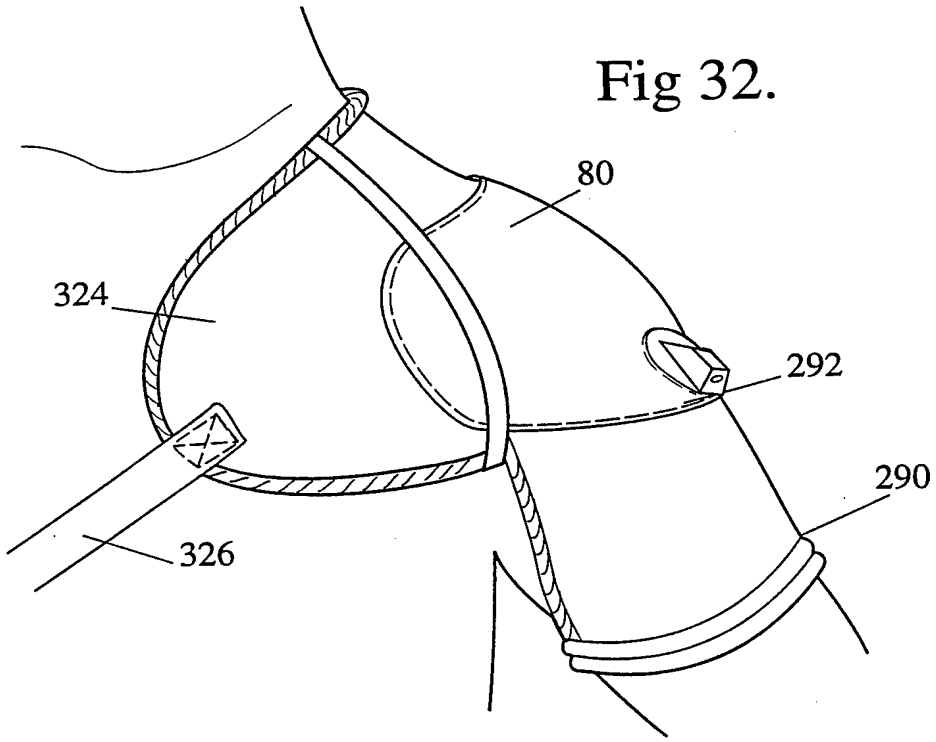

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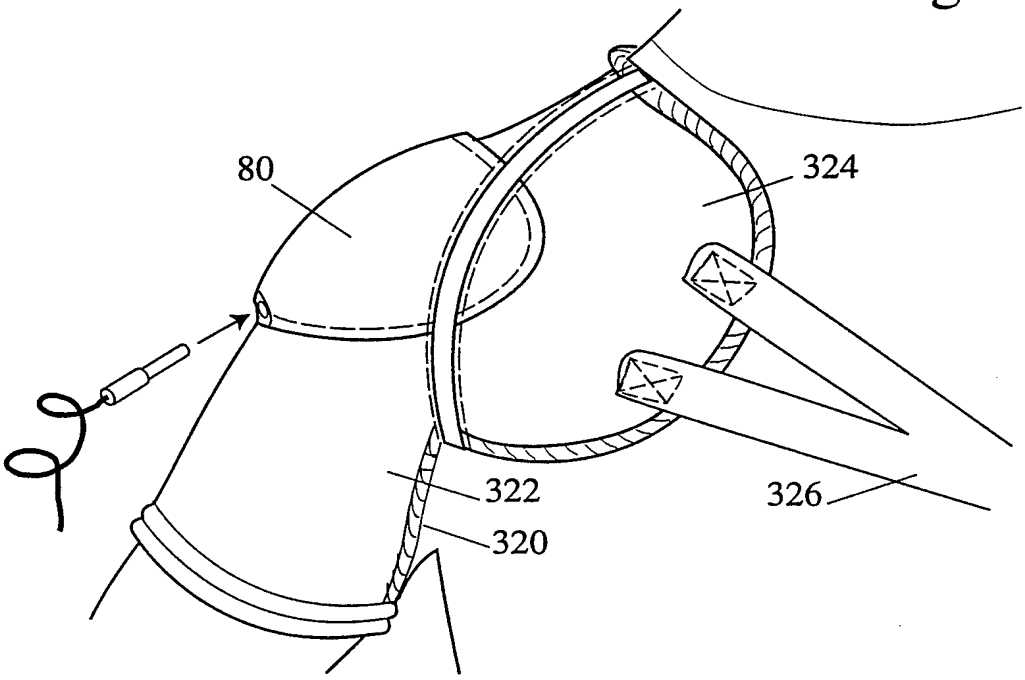

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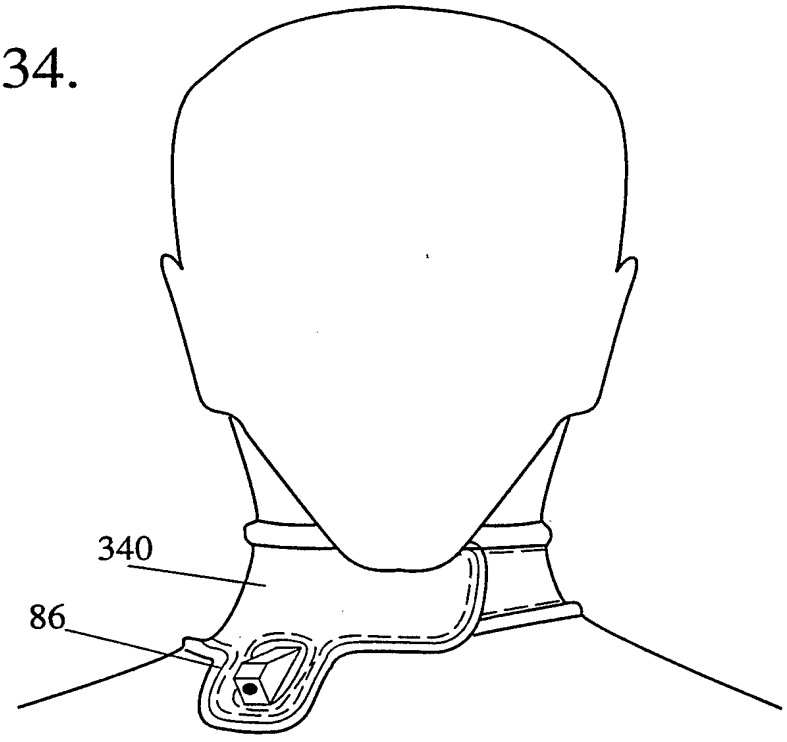

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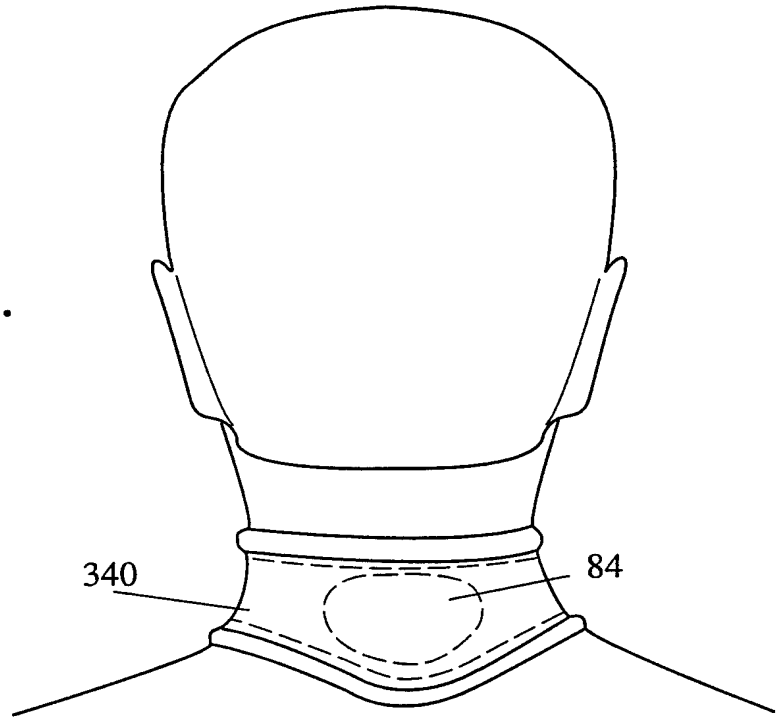

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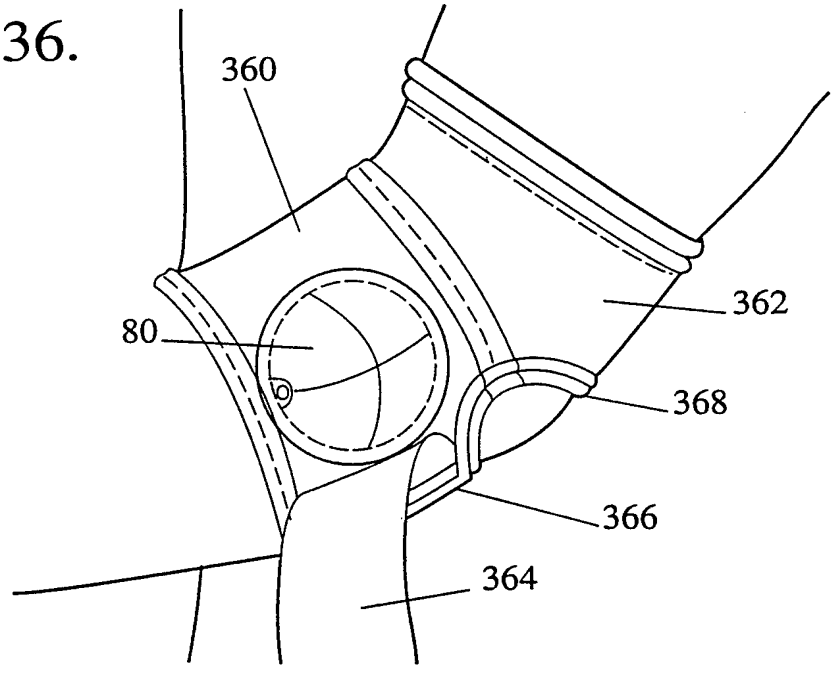

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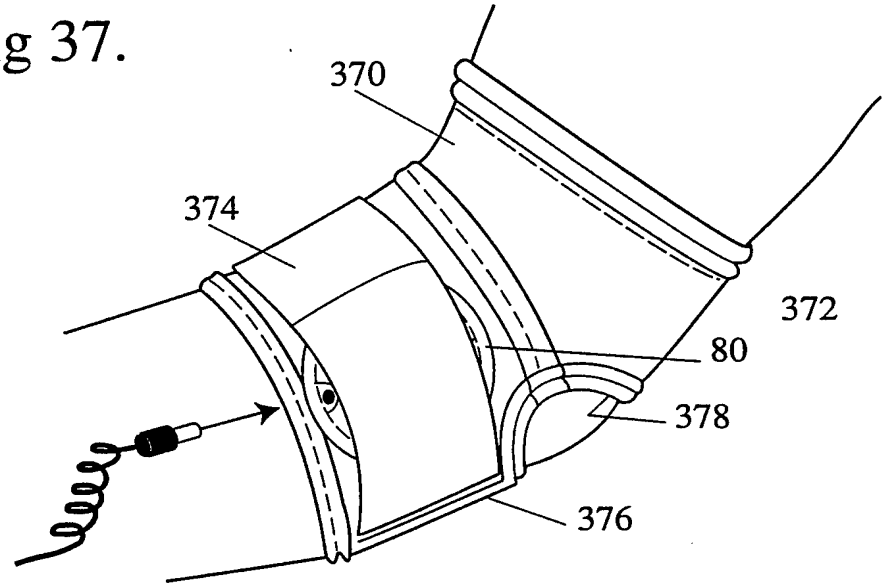
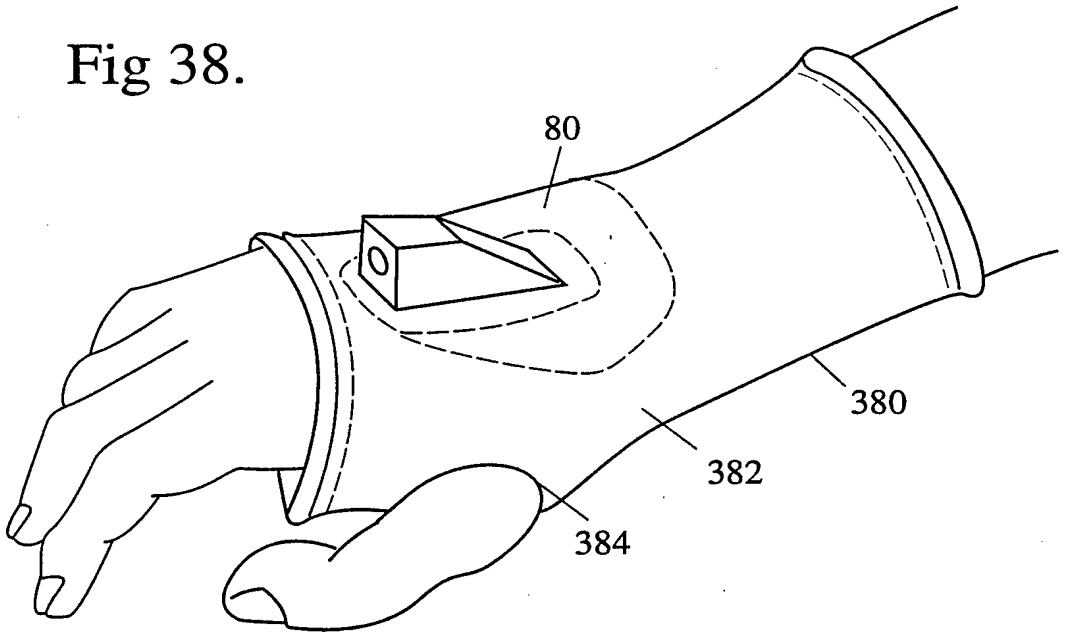


Fig 38.



INTERNATIONAL SEARCH REPORT

International application No.
PCT/AU 95/00208

A. CLASSIFICATION OF SUBJECT MATTER
Int. Cl.[6] A61N 2/04

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC A61N 2/04, 2/02, 1/42

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
AU: IPC as above

Electronic data base consulted during the international search (name of data base, and where practicable, search terms used)
DERWENT and JAPIO: puls:

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to Claim No.
X	AU 73231/87 B (610497) (LTI BIOMEDICAL, INC.) 26 November 1987 whole document	1-5, 7-10, 12, 17
X	AU 18411/83 A (PILLA et al) 8 March 1984 page 4, line 9 - page 6, line 30; page 10, line 26 - page 11, line 22; Figs 1-3	1-10, 12, 17
X Y	US 4266533 A (RYABY et al) 12 May 1981 col 4 lines 1-53; col 6, lines 13-19; col 7, lines 9-16; col 13 line 31 - col 16 line 43; col 19 lines 33-42; Figs 1-11	1-4, 7, 10, 13, 15, 17 1-4, 7, 17

[X] Further documents are listed in the continuation of Box C.

[X] See patent family annex.

* Special categories of cited documents :

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Date of the actual completion of the international search	Date of mailing of the international search report
30 June 1995	10 JULY 1995 (10.07.95)
Name and mailing address of the ISA/AU AUSTRALIAN INDUSTRIAL PROPERTY ORGANISATION PO BOX 200 WODEN ACT 2606 AUSTRALIA Facsimile No. 06 2853929	Authorized officer M.E. DIXON Telephone No. (06) 2832194

INTERNATIONAL SEARCH REPORT

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

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END OF ANNEX